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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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Analyzing Leadership in Global Health Governance

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Rhetoric around the need for more and better leadership is ubiquitous in contemporary global health governance, yet there has been little articulation of what type of leadership is required, who might play leadership roles, and in what fora leadership might be exercised. Global health governance has widely been seen as a policy space characterised by a multiplicity of (often competing) actors with no overall authority. Nonetheless, major accomplishments exist, and in some cases there are impressive levels of collective action to address particular health problems. We argue that leadership provides an important lens for understanding how goals are met in global health governance. Drawing on the existing literature on global health governance and leadership and agency in international relations, we set out in this paper a framework for analysing leadership in global health governance. Crucially, we argue, such a framework must be specific enough to be operationalised in terms of a program of research and at the same time broad enough to capture a wide variety of different sources, sites and forms of leadership – including the roles played by 'hidden leaders' who are seldom acknowledged in mainstream analyses of global health politics.

INTRODUCTION

Global health governance continues to be subject to regular calls for reform. Demands for changes in the institutional architecture, greater co-ordination between the myriad agencies involved, and closer partnership between public and private actors are commonplace in contemporary global health discourse. A recurring theme in these discussions has been the apparent need for more and better leadership. Leadership rhetoric, indeed, is everywhere: at the international level it is seen as vital to the ongoing project of WHO reform;[1] at the national level as a key factor in developing countries delivering effective health policies and programmes.[2] Yet whilst more and better leadership is commonly seen as the solution to these problems and a host of others, there is little articulation of what type of leadership is required, who might play leadership roles, and in what fora leadership might be exercised. Instead leadership has taken on the status of an unattainable panacea, its absence being both an explanation and an excuse for the overall system's failure to adequately address health needs.

The purpose of this paper is twofold. First, we explore the analytical utility of 'leadership' as a lens through which to examine global health politics, in particular its value in helping to reveal how things 'get done' in global health (or, in too many cases, why they don't). Second, we seek to operationalize leadership as means of analysing global health politics, in doing so, arguing that existing work on agency and leadership in International Relations (IR) can provide us with some of the conceptual tools we need to understand leadership in global health. The paper argues that a focus on leadership delivers some insights into the practice of health governance, not least around the setting of global health agendas. However, such an approach also brings dangers – in

particular the risk of reifying the roles played by prominent (and often self-proclaimed) global health leaders (the vast majority of whom are white men from the Global North), in so doing obscuring the roles played those who do not fit this image of who a leader is, or how and where he (or, less frequently, she) should act. To guard against this danger, we propose a maximalist conceptualisation of both leadership and global health governance which first understands leadership *as a practice* rather than as a position to be held and retained; and which secondly takes a broad view of *where* leadership in global health is practiced, looking beyond the traditional policy hubs of Geneva, New York, Washington DC and Seattle, and instead viewing global health as a genuinely *global* governance arena.

The paper proceeds in four sections. In the first we explore what existing studies of global health governance tell us about agency. In the second section the paper goes on to consider what we know about leadership as a particular form of agency in global health governance, arguing that whilst there are some insights to be gleaned, leadership has not to date received sufficient analytical attention. In the third section, we suggest that work outside of global health has some important lessons to offer, in particular the literature on agency in IR, and also the existing work on leadership in supra-national negotiation processes. Finally, building upon the literatures examined in the preceding sections, the paper proposes a five-part matrix for analysing leadership in global health governance which is sensitive to the varied forms, sites and sources of leadership which exist in practice.

AGENCY AND GLOBAL HEALTH GOVERNANCE

Scholars in global health have done a good job of mapping and describing the developing and highly complex architecture of global health governance in which agency (in the sense of the ability to create change) is highly diffused. We have good accounts of the variety of actors that play governance roles, of the ways in which new actors have entered this policy sphere over the last couple of decades, and of some of the material and ideational forces that have shaped global health governance. For instance, we know quite a lot about the characteristics, approaches and activities of most of the major global health governance actors, including the WHO,[3] the UN,[4] the World Bank,[5] the IMF,[6] the WTO,[7] NGOs,[8] public-private partnerships,[9] and old and new forms of philanthropy[10] - not to mention the role of states in the contemporary globalisation of health policy.[11] There have also been a number of works that have looked across global health governance as a field and have tried to understand how the pieces of this complicated jigsaw fit together.[12]

From this literature, it is possible to draw out three findings about the forms and sources of agency in global health governance which are commonly identified.

The first – certainly not unique to the health sphere – is about the power of money. The ability to finance global health projects and institutions is a key source of agency, not least through the ability to dictate how that finance is used. Perhaps the best example of financial resources being a source of agency in global health is that of the Bill and Melinda Gates Foundation. Famed in global health circles for having a larger budget than the WHO, the Foundation's Global Health Program has exhibited tremendous influence with regard to its ability to finance activities and institutions directly, influence agendas, and secure a presence in high-level global health summits and the

World Health Assembly. It is true that attributing this agency solely to finance is a simplification - the personal profile and gravitas of Bill and Melinda Gates also play a part, as does the reputation of the experts who work with and for the Foundation - but it is the Foundation's ability to put its financial muscle behind those issues that it prioritises (inextricably linked to those issues in which Bill and Melinda have a personal interest) that has made it one of the most powerful and influential non-state actors in global health governance.[13] More traditional international financing organizations such as the World Bank are also able to exercise agency as a consequence of their ability to mobilise funds, in the case of the Bank through core International Development Agency (IDA) or International Bank for Reconstruction and Development (IBRD) project funds as well as multi-donor trust funds for specific health priorities. Again, the World Bank's agency cannot be attributed solely to its ability to financially support specific health projects. The fact that it has a long-standing country presence and well-developed relationships with both governments and United Nations agencies in-country also gives it tremendous influence.[14] Thus though the Bank may not always bring the most money to the health table, its combination of finance, in-country longevity and proximity to government provide a unique source of agency in global health.

Conversely, a reliance on external finance can seriously inhibit an actor's ability to exercise agency. The cuts to the WHO's core budget, for example, have been widely seen as having reduced its scope to exercise agency in global health.[15] The institution continues to be able to articulate health needs, concerns and priorities but often lacks the necessary finance to support work in specific areas or to carry out the initiatives that it might wish to pursue (unless it can persuade governments to support them through Extra-Budgetary Funds). Even the organization's 'softer' normative role seems to be under threat as the lack of funds impacts on its knowledge production capacity, and the range and scope of its activities comes under increasing scrutiny from its funders, some of whom desire a narrower, more technically-focussed and less politicized WHO.

A second agency-related finding to be drawn from studies on global health governance is a tendency for new institutions to be created when existing ones are thought to be failing. From the turn of the millennium, global health has seen a rapid and sprawling growth of new multilateral institutions, non-governmental organisations, public-private partnerships, and product development partnerships. Some of these, such as the Global Fund - which was intended to fill a gap in rapid financing to combat 'the three scourges' of HIV/AIDS, malaria, and tuberculosis - were created specifically because of a belief that existing institutions such as the WHO, UNDP, or the World Bank were not capable of delivering effectively.[16] Elsewhere, new organizations have grown up in response to the availability of funding in particular areas, a phenomenon seen most clearly around HIV/AIDS. This was certainly the case with the growth of the NGO 'industry' in countries where the disease had high prevalence and was targeted for international financial assistance.[17]

Again, such emphasis on "the new" can restrict the space in which the incumbent institutions of global health, such as the WHO, can exercise agency. Some see this as a good thing, as the WHO is forced to compete with other agencies and address some of the problems that people see with the institution. On the other hand, it plays into the idea that the WHO is a failing institution, reducing the space the organization has to act on its mandate and its potential to exhibit the agency it is often accused of lacking, creating a vicious circle of underachievement and under-valuation.

The increasing number of institutions has also divided the overall global health pot among a greater number of actors. During the early years of global health's institutional boom, this was less of a problem as it coincided with a dramatic increase in overall funding for global health. Partnerships such as the Global Fund and GAVI were created and given large budgets with which to work. Now budgets are tightening, and there seems to be a reduction in the rate of institutional creation. Those that have already been created, however, are presumably here to stay. As a result, global health actors are increasingly being forced to compete with each other to maintain their funding levels.

The third finding we distil from the global health governance literature is that the bewilderingly complex, ad hoc and non-hierarchical institutional architecture has created problems. In terms of setting a consistent and deliverable global health agenda the problem, arguably, is a surfeit rather than a lack of agency. This is particularly evident with regard to overlapping mandates, competing aims and objectives, and double-dipping in the pot of project financing. Multiple initiatives have been established over the last 10-15 years in an attempt to co-ordinate the work of different global health actors. These include donor partnership groups or meetings; principles such as the 'three ones' articulated by UNAIDS to co-ordinate the global AIDS response in-country; technical working groups; the designation of lead agencies in specific sectors; and major global agreements such as the Paris Declaration. However, despite the range and number of initiatives – which in themselves demonstrate how multiple mechanisms of co-ordination can complicate the problem further – problems of overlap and 'mandate creep' abound. The multiplicity of actors also imposes significant transaction costs, not least on recipient countries. Such countries have to manage the different interests, objectives and demands of their numerous 'partners', a task that can stretch already under-resourced government capacity and can lead to a shifting of priorities towards those health issues seen as popular or appealing to external donors. Whilst it could be argued that the existence of multiple donors can actually enhance the agency of developing countries as they have an opportunity to play different donors and different tranches of aid financing off against each other, in practice such complexity frequently generates a management headache for governments and can contribute to a distortion of priorities of an individual state's health objectives.

These three agency-related issues – the link between finance and agency; the creation of new institutions; and the potential for too much (and too often uncoordinated) agency - have intersected with underlying structural factors to present a number of challenges to contemporary global health politics. Global inequalities (both economic and heath inequalities, the two of which are closely linked) have not been tackled. The need to address the social determinants of health has been the subject of much rhetoric, but far less concrete action. The global financial crisis is also having an impact on global health. ODA for health is starting to drop as other areas such as infrastructure begin to increase, some donors have withdrawn from partnerships such as the Global Fund, and a perception of 'aid fatigue' amongst the wider public is growing, particularly with regard to diseases such as HIV/AIDS, challenging the assumption that global health financing will always feature highly in the public conscience. This is all occurring at a time when the position of health in international development financing is being discussed in the context of the 2015 Millennium Development Goal (MDG) deadline. Three of the eight original MDGs were health-

related, and much of the investment in global health over the first decade of the new millennium was driven by that commitment. Questions remain, however, over the extent and scope of health's representation on the post-2015 development agenda. The fact that global health is susceptible to being portrayed as bloated, with multiple (and at times competing) actors increases the danger that it may find itself slipping down the list of priorities.

Whilst these three insights are commonly found across the existing literature on global health governance, another thing that characterises the vast majority of these works is a tendency to take institutions (or partnerships between institutions) as the principle agents of global health governance. As a result, the agency of individuals working both within and outside of these institutions is often overlooked. This corporatist approach to institutional agency has the merit of simplifying the analysis of what is, even in simplified form, an overwhelmingly complex policy space. At the same time, however, it brackets off much of what we know about the practice of institutional politics, for example that bureaucrats can wield power and authority,[18] that personalities (and inter-personal group dynamics) contribute to determining political outcomes,[19] and that institutions do not always behave in a coherent fashion – nor do they necessarily behave in the ways their creators intended.[20] A focus which privileges institutions and their outputs, therefore, risks undervaluing the processes through which those outputs are produced – as a consequence missing some important determinants of how things 'get done' in global health governance. A focus on individuals and their exercise of leadership, we argue, has much to contribute here.

LEADERSHIP IN GLOBAL HEALTH

Where scholars have examined individual agency, they have exhibited a strong tendency to focus on particular types of individual - predominantly white, Western and male - who have, according to mainstream accounts, shaped and led the current discourses and practices of global health. There have, for example, been a number of studies of individuals who head (or hold other senior positions in) global health institutions, including individuals such John D Rockefeller,[21] Gro Harlem Brundtland, Lee Jong-Wook,[22] Bill Gates,[23] Jonathan Mann,[24] and Peter Piot.[25] We also know about the ways in which high-profile celebrities such as Bono have aligned themselves to global health issues. Senior politicians have also attracted attention as individual agents capable of shaping global health. George W. Bush, for example, played a widely-noted leadership role in the scale-up of anti-retroviral treatment for people living with HIV/AIDS (as well as supporting prevention strategies) through his President's Emergency Plan for AIDS Relief (PEPFAR).

In some cases these leaders have been widely praised for their influence on global health as a policy field. Jonathan Mann, for example, has been credited with a crucial role in the development of global responses to AIDS, and in particular with promoting a human rights-based approach to AIDS and other health issues. Elsewhere, judgements on the leadership of particular individuals have been more mixed. Bill Gates has been the subject of criticism in some quarters despite his foundation's huge investment in global health. Perhaps more predictably, George W. Bush has divided opinion. Whilst PEPFAR is seen by many as a key part of the effort to achieve universal access to ARVs, the leadership Bush demonstrated was not without controversy. Prevention

programmes were originally funded on the condition that the 'C' of ABC – Abstain, Be faithful, use a Condom – was not used. PEPFAR programmes were also subject to the 'global gag rule' (repealed by Obama in 2009) that prevented US aid from going to any organisation that provided or offered services related to termination of pregnancy, and only organisations and groups that explicitly opposed prostitution were eligible for funds.[26] These conditions led to considerable consternation among parts of the global health community, particularly among those working on reproductive health and women's health.

Similar controversies have arisen around political leaders who have deliberately attempted to challenge the status quo. The ex-Minister of Health for Indonesia, Siti Fadilha Supari is a prime example. In seeking to challenge the global virus sharing system that is a fundamental part of influenza vaccine production, Supari was seen by some as playing a leadership role on behalf of the developing world in contesting a system which resulted in many of the countries supplying virus samples (including Indonesia) in effect being priced out of purchasing the vaccines that those samples were used to produce. Others, however, saw Supari's tactic of withholding virus samples as highly problematic. Even some of those who supported her point in principle were uneasy about the tactic of effectively 'holding the world to ransom' through the refusal to share samples.[27]

Leadership, these examples show, is often controversial and – despite the rhetoric which presents leadership as a solution to global health ills – it is not necessarily an unproblematic good. But whilst scrutiny of the roles of such high-profile figures as Supari, Bush, Gates and Mann is an important part of analysing global health politics, it is far from the whole story. Indeed, we argue here that the focus on these high-profile figures draws attention away from the less obvious 'hidden leaders' who also play instrumental roles in creating and implementing global health programmes, subverting or reinforcing global agendas, and shaping the outcomes of policy discussions in a range of different countries and contexts.

Partly, this shortcoming is a result of the spaces and fora in which we generally think of global heath as being governed. High profile conferences and summits generate attention around particular types of leaders, but in the process divert attention away from those who do not attend (or may not even have heard of) such events. Likewise, the clustering of global health institutions in Geneva (and New York, Washington DC, London and Seattle), reinforces a particular view of who is governing global health and where that governance is happening. These spaces and the agents who operate within them are of course important and should not be ignored. Yet one of the key insights of the first generation of scholars of 'global governance' was that governance happens everywhere. James Rosenau, for example, wrote in the first issue of the journal *Global Governance* that

> The United Nations system and national governments are surely central to the conduct of global governance, but they are only part of the full picture. Or at least in this analysis global governance is conceived to include systems of rule at all levels of human activity - from the family to the international organization - in which the pursuit of goals through the exercise of control has transnational repercussions. The reason for this broad formulation is simple: in an ever more interdependent world where what happens in one corner or at one level may have

consequences for what occurs at every other corner and level, it seems a mistake to adhere to a narrow definition in which only formal institutions at the national and international levels are considered relevant.[28]

But whilst the global health governance literature has clearly[29] built upon the thinking of Rosenau and others on global governance, it has too rarely taken up the challenge to see what is happening in the more obscure corners and at the less high-profile levels.

There are, however, some notable exceptions. Sanjoy Bhattacharya's detailed historical work on Smallpox eradication in India, for example, highlights how Indian health workers and research partners were pivotal to the disease's global eradication. As Bhattacharya argues, "it would be simplistic to reduce the worldwide smallpox eradication programme to the ideas and actions of a handful of individuals or, indeed, the institutions to which they were associated."[30] Yet, as he also highlights, this is what has often happened, with the contributions of those operating at the national and sub-national levels (especially within the developing world) often being neglected in accounts of the history of smallpox that have tended to reify individuals working with Western institutions such as CDC.[31] As Bhattacharya notes,

> it is no surprise to witness organised efforts on the part of government and nongovernment agencies to highlight their contributions to this memorable triumph. The danger, of course, is that these exercises will chronicle relatively few voices and then present them as being representative of the "reality" of the eradication programme as a whole; such an approach is to be avoided, although these individual voices are, of course, valuable. The global project to limit the spread of variola, as it evolved in the 1960s and 1970s, involved countless participants. It was simultaneously an international and local entity, and each avatar had several constituents.[32]

The lesson we take from the work of Bhattacharya (and others who have sought to reveal the activities of what we here term 'hidden leaders') is that understanding how things 'get done' in global health (or, to use the language of leadership studies, how the agency of multiple actors can be harnessed in pursuit of common goals) requires us to take into account *both* high-profile 'visible' leaders *and* often-ignored 'hidden' leaders. Failing to take both into account risks providing a skewed picture of how global health governance works, and also brings the other problems we noted above in relation to the reification of a particular type of (usually white, Western, male) leader. This, it seems to us, runs counter to the whole idea of health (and health governance) as 'global'. A key requirement for the analytical matrix that we present in the final section of the paper, therefore, is that it must provide a means of examining the influence of both visible and hidden leaders in global health politics.

AGENCY AND LEADERSHIP IN INTERNATIONAL RELATIONS

First, however, we look beyond the global health governance literature to examine what insights from other fields might provide conceptual tools that can contribute to the building of a framework for the analysis of global health leadership. This involves, in

particular, understanding agency in at the international level and then understanding leadership as a particular form of individual agency.

Agency

Any understanding of leadership in the international sphere has to be based on an underlying conception of agency. Questions of agency are one of the central pillars of IR scholarship. Historically, discussions of agency in mainstream IR tended to focus on states as actors. The discipline's primary interest in the inter-state level of analysis made this in many ways a natural choice: states go to war, states sign treaties; states create international organizations; and states adopt foreign policy positions. Of course, as David Williams argues,[33] such 'black-boxing' of the state – the US gives money to HIV/AIDS; the UK prioritises maternal child health – is generally recognised even by those who perpetuate it as a form of intellectual 'shorthand'. Yet the use of such shorthand is nevertheless seen by many IR theorists as defensible, even desirable. For Kenneth Waltz, for example, states were the fundamental units within the international system. The properties, characteristics and make-up of those units did not matter much in his system-level approach to theorising international politics; only the position of units within the system mattered.[34] Individual human agency was less important to Waltz's system-level theorising because personalities and behaviours can change whereas structures of the state and the system in which states operates endure: 'abstracting from attributes of units means leaving aside questions about the kinds of political leaders, social, and economic institutions and ideological commitments states may have.'[35] Alexander Wendt, coming from a very different theoretical position, argues that agency can ultimately only be attributed to individual persons, although he goes on to make the case that states acting within the social environment of international society can be treated as analogous to individuals and understood as persons with moral roles and responsibilities as well as legal and judicial claims to sovereignty.[36]

It would be wrong, however, to portray IR's engagement with agency as lacking in nuance: even amongst those who see states as the primary agents, it is certainly true that there have been important and influential debates and a growing interest in the question of 'who governs'.[37] Two examples are the agency-structure problem/debate/problematique and work that has examined the question of *which* states are able to exercise agency on the international level. The former debate, which essentially arose from the perceived failure of structure-driven (often structural realist) accounts of international politics to deal with major changes such as the end of the Cold War, resulted in new theories about the relationship between agency and structure, and to disagreements over the relative weight that should be given to each in explaining political outcomes. The latter stream of work has used the concept of agency as a normative framing for investigation bringing 'peripheral' states often seen as subject to, not agents in, international relations to the fore. This has particularly been the case with regard to African agency.[38] African states have often been seen as something exceptional - not really states in the western conception of the term. Despite the fact that they are a politically and socially diverse set of polities, the history of colonialism has tended to lump African states into one (problematic) category. Emphasising agency as a lens through which to investigate African states' roles in international relations, such work

seeks to overcome the idea of Africa being 'acted upon' by the international system rather than African people, states, and collective endeavours acting in their own right.[39]

As we go on to discuss further below, leadership is something that is practiced by individuals – an idea which makes it problematic to apply these traditional ideas about agency in IR. Elsewhere, however, IR scholars *have* looked at individual agency. For example, Colin Wight, contra-Wendt, argues that a personification of the state which treats states as "individuals writ large" obscures individual human agency within the state. As Wight says, 'this seems to be little different from previous forms of structuralism that essentially write out individuals and treat them as ciphers for structural forces' leaving little room for individual agency and an assumption on the sources of collective agency that gives states the space to act.[40] Whilst this is a fair critique of some of the system-level theorising of Wendt (and indeed of Waltz and others) there is, of course, also a long history of 'looking inside the state' to understand 'what makes them tick', from Graham Allison's classic *Essence of Decision*[41] to today's work on foreign policy analysis.

There has also been a good deal of work that has examined individual human agency outside the context of the state. Indeed there is a widespread acknowledgement amongst most IR theorists that states are not the only significant actors in contemporary international politics, even if some continue to prioritise states in their analysis. One example of such work is the literature that has examined individual agency within international institutional structures, perhaps most notably within international organizations. Robert Cox's essay on the 'executive head'[42] was a classic statement of this kind, and it has been followed by a literature that has examined the bureaucracies of international organisations and how those bureaucracies can exercise agency both corporately and through the actions of individuals within them[43] – including literatures examining the holders of specific positions such as the UN Secretary-General as actors in world politics capable of exercising significant degrees of agency.[44] Work on civil society's role in international relations has also paid attention to the role of individuals, including celebrities and other high-profile actors.[45]

Notwithstanding the discussions over who or what has agency, there has been relatively little conceptual examination of what 'agency' in the international sphere actually means – especially when compared to the emphasis that the discipline has placed on understanding structure.[46] As Supreme Court Justice Potter Stewart famously said of hard-core pornography, there is a sense that we all know agency when we see it, even if it is rarely actually defined. Colin Wight, however, proposes a conceptualisation of agency that is 'multi-layered' and that "explicates the fragmented nature of this problematic concept."[47] In doing so he attempts to avoid falling into what he sees as the trap of personifying the state by taking into account three levels of agency: agency as the capacity to (intentionally) do something (which Wight calls $agency_1$); agency in the sense that those with the capacity to do something are acting as 'agents' of something other principal ($agency_2$, which locates agents within a particular socio-cultural context); the third level ($agency_3$) describing "'position-practice-places' which $agents_1$ inhabit on behalf of $agents_2$."[48] Wight's attempt to clarify this through an example runs as follows:

> An example of the way in which these three levels of agency are complexly related to each other can be drawn from an examination of the nature of a diplomat. X,

our putative diplomat, is at once an agent$_1$, he has a unique personality which is itself a consequence of his unique personal make-up and the many forms of agency$_2$ and agency$_3$ which have shaped and formed X throughout his life. Nonetheless, at a given point in time X assumes a specific 'positioned-place-practice' within *one* of the realms of agency$_2$ (the diplomatic service) which X inhabits. This 'positioned-place-practice' delineates the function that X now plays in this particular form of agency$_2$. Yet X, due to his potential as an agent$_1$ – and his participation in differing forms of agency$_2$ – is never an automaton simply practising in accordance with his place in the positioning.[49]

Leadership

Getting to grips with understanding different levels of agency, the role of individuals in the international sphere, and the relationship between individual agents and the states or other bodies on whose behalf they act is crucial for our purposes because, as Oran Young agued, leadership is inherently an activity carried out by individual human beings. He noted (with some clear foreshadowing of the quote from Wight above) that

> the recent emphasis on hegemony and, more generally, structural determinants of collective outcomes in international society has had the effect of diverting attention from the roles that individuals play as leaders who are able to exercise significant influence over processes of institutional bargaining. To avoid the resultant pitfalls of reification, it is important to bear in mind the relationship between individuals and collective entities, such as states and international organizations. Those who become leaders in institutional bargaining frequently act in the name of or as agents of states or international organizations. But in the final analysis, leaders are individuals, and it is the behaviour of these individuals which we must explore to evaluate the role of leadership in the formation of international institutions.[50]

But even if we accept the basic premise that leadership is practiced by individuals, there are still plenty of conceptual difficulties in applying leadership as a concept. Leadership Studies has struggled for decades to define and agree on the use of the term. Fleischman et al[51] identified 65 different classification systems that had been developed at that point, and there remain divides at the most fundamental levels, including over whether leadership is about the shaping of a group process; whether it is a trait that individuals either do or do not possess; or whether it is a particular form of behaviour.[52]

Each of these understandings has been evident in the long history of works on political leadership, which long predate the recognition of any formal discipline of 'leadership studies'. For a long time 'big man' theories of the charismatic political leader dominated. Over time, however, there has developed a literature of more direct relevance to the study of global health governance which has sought to understand the broader and more nuanced role of leadership (and associated phenomena, such as policy entrepreneurship) in policy processes,[53] including in supra-national settings. This literature has often foregrounded the roles played by individuals (at least, as we shall see, by particular types of individual).

Oran Young made a helpful distinction between structural leaders (who are "experts in translating the possession of material resources into bargaining leverage"); entrepreneurial leaders (who rely on "negotiating skill" to make agreement possible); and intellectual leaders (who rely on "the power of ideas to shape the thinking of the principles"). All of these forms of leadership, Young argues, play a role in the reaching of international agreements.[54] As to the identities of those leaders, Young argues that structural leaders "are almost always representatives of major actors involved in bargaining processes", but that those who exercise the other forms of leadership can be far more diverse: he cites, for example, scientists who helped shape global action on ozone depletion,[55] whilst others have examined those who hold formal leadership positions, such as chairs of negotiation processes.[56]

Here, in the context of international negotiations, leadership is essentially being understood as a social process in which leaders (using whichever form of leadership) attempt to influence those (usually states) who have the power to either agree or not with a particular negotiated outcome. The aim of leadership, therefore, is to bring multiple actors together around a common goal. The means by which the different kinds of leaders Young identifies attempt to create that convergence of opinion vary – using resources such as leverage (structural leadership); using persuasion and bargaining tactics (entrepreneurial leadership); and using ideas to shape the way in which participants understand the issue and their own interests (intellectual leadership). In each case, however, the overall aim is to bring the various parties involved in a negotiation to agreement.

For our purposes – attempting to better understand how things 'get done' in global health governance– a similar understanding of leadership as a process of harnessing the agency of multiple actors best provides us with the tools that we require. Indeed the definition of leadership that we adopt here is simple (although in some ways deceptively simple): following Northouse[57] we define leadership as "a process whereby an individual influences a group of individuals to achieve a common goal". We also stress that it is important to take into account the fact that such influence takes place in a specific context, place or setting. Others who have grappled with the issue of leadership in international politics have often settled upon similar definitions - Joseph S. Nye for example, describes leadership as "mobilizing people for a purpose."[58]

There are, however, two remaining (linked) hurdles to operationalising the idea of leadership in relation to global health governance. The first is that there is more to global health governance than formal negotiations. To be sure there are formal international negotiations over health issues, but governance processes are much more diverse than this: individual organizations have their own policies; non-state actors play important governance roles; national governments (and sub-national entities) make decisions and undertake actions that have international consequences; and a conglomeration of individuals shape or subvert practices of global health in the implementation and interpretation of policy directives and ideas. Understanding how things 'get done' also requires us to look at policy implementation, not just policy making. Therefore, Young's work – and that of a number of others who have also focussed on formal negotiation processes[59] - gives us some useful tools, but addresses only part of the picture.

Second, and following on from this, even Young's diverse group of intellectual leaders (including renowned scientists and others who might be able to influence

international negotiations) does not cover the breadth of those that we include in our category of 'hidden leaders', many of whom would have no access to international negotiations but who nevertheless play a role in the governance of global health. As we noted above, accounts of agency and leadership in global health have tended to focus on organisations – international institutions or community based organisations for example – or prominent leaders that fit a particular mould. However we argue that 'hidden leaders' play a fundamental role in getting things done in global health that whilst not prominent in mainstream accounts of global health policy show clear leadership in engaging followers and mobilising around global health issues – just as with the Indian health workers and others in Bhattacharya's history of smallpox eradication.

AN ANALYTICAL MODEL FOR INVESTIGATING LEADERSHIP IN GLOBAL HEALTH GOVERNANCE

In outlining an analytical model for investigating leadership in global health governance we build on the insights to be derived from the works of Young, Wight and others, but use them in a way which is at once specific enough to be operationalizable in terms of a program of research and at the same time broad enough to capture a wide variety of different sources, sites and forms of leadership. Our starting point is that that we can best understand leadership in the international sphere as a specific form of agency. But whilst it is individual human beings who actually exercise leadership, they will be doing so within the particular context of their role ('positioned-practice-place' in Wight's terminology) and often on behalf of a principal (for example they will be acting as a representative of a particular state, international organization, NGO or affected community). As Wight reminds us, however, their individual characteristics as an agent$_1$ with particular life experiences and histories will also matter.

Given the number of institutions that play global health governance roles at all levels, and the huge number of people involved in them, individual agency is obviously a hugely widespread phenomenon involving many thousands of individuals across the world. Leadership (at least successful leadership) is, however, a more limited phenomenon. Leadership requires the individual agent to be pursuing a particular purpose (related to global health), and it also requires intent – a conscious effort on the part of an agent to turn other agents into followers. Who these leaders are in practice is an empirical question – but one which is, we argue, 'researchable' through applying the matrix we set out below to particular areas of global health governance (for example, to examine leadership around a particular disease or policy).

The identity of leaders' (intended) followers is another empirical question, but there are some general things that we can say. And here things become even more complex because there are multiple forms of individual and collective agents that leaders may wish to influence: governments; publics; philanthropists; private corporations; international organizations – and the list could go on. What unites these putative followers is that they must also possess agency (either individual or collective). Thus the goal of a leader in the context of global governance is to *harness the efforts of multiple agents in pursuit of a common goal*. Why some leaders succeed and some fail in harnessing the efforts of multiple agents – what determines their success or failure - is yet again an empirical question. There are, however, indications in the literature

about some of the factors that may contribute to successful leadership including power, charisma, the existence of a conducive external environment[60] and the ability of leaders to successfully adapt their message to the social context.

The logic underpinning our belief in the utility of leadership as an analytical concept is, briefly stated, this: global health governance has widely been seen as a policy space characterised by a multiplicity of (often competing) actors with no overall authority capable of setting, still less enforcing, a coherent agenda. Yet despite this things do 'get done' in global health governance, and in some cases there are impressive levels of collective action designed to address particular health problems. Such things do not emerge by chance. Leadership, we argue, is one of the key factors in the harnessing of multiple agents to produce such collective action outcomes.

Of course, structure also matters. Leaders are agents acting within (and constituted by, as well as constituting) a particular structure. The study of leadership must therefore incorporate this broader context and recognise that "individual leadership approaches in conjunction with contextual and situational approaches are indispensable for understanding causality in international relations and comparative politics today."[61] To understand leadership, therefore, we propose an analytical model that proceeds from the insights of Wight, Young and others but which takes into consideration the need to recognise hidden leaders, which is sensitive to structure and which connects leadership to specific outcomes – desired or otherwise. As such we propose five analytical points on which leadership can be analysed within global health: i) identity and positionality; ii) intent; iii) context; iv); form and v) outcome.

A Five-Point Matrix for Analysis

1. *Identity and positionality.* The first question concerns who is exercising leadership around a particular health issue, policy etc. and (where relevant) on whose behalf they are exercising that agency (e.g. is it as a representative of a state, an NGO or something else). The ability of particular individuals to exercise effective leadership is of course shaped by this positionality, but also by a wide variety of other factors including geography, personal wealth, expertise, cultural relations and chance. As Bill Gates Sr. (father of Bill Gates) has pointed out, Bill Gates would not have become the figure we know today if he had been born in a developing country.[62] However that is not to say that if Bill Gates had been born in Tanzania he could not have exhibited leadership. He may not have established Microsoft or his Foundation, but he could still have mobilised the people around him in pursuit of a specific outcome. Such an outcome may not have had comparable world-wide coverage or impact but it would remain a position and context specific outcome that may have impact given his position and presence. Hence even though identity and positionality are crucial in understanding the constraints on leadership, they should be used to reveal rather than obscure different forms, sources and sites of leadership.

   Methodologically speaking, there is clearly a challenge to be addressed in identifying those who are exercising 'hidden leadership'. If they are hidden, how can we find them? Whilst it is important not to underestimate this difficulty, our contention is that it is one that can be addressed, and that

designing research in a way that is sensitive to the existence of hidden leaders can enable their governance contributions to be brought out into the open (subject to the caveats we address below about the necessity of leaders remaining hidden in some political contexts). Careful empirical tracing of particular policy making and implementation processes is, we would argue, the key to identifying hidden leaders and tracing their contribution. Bhattacharya, whose work on Smallpox eradication we discussed earlier, serves as a model here: beginning with an awareness that events in Geneva and Atlanta cannot explain everything about the ultimate success of the global Smallpox eradication campaign leads to a project design that combines what is happening at the global level with a careful empirical analysis of what is happening at national and sub-national levels, in the process revealing a whole new set of agents who are playing important (leadership) roles. The challenge for those working in global health governance, therefore, is to expand their horizons beyond the traditional 'policy hubs' and to better engage empirically with global health governance on a more genuinely global basis.

2. *Intent*. Once leaders have been identified, the issue of their intent can be investigated. Questions include why they took on a leadership role around a particular issue, what their motives were, how these activities fitted with their professional commitments and roles, and how they strategized about the ways to forward a particular agenda and to create followership. Institutions and actors are often keen to take the credit for various successes in global health and to distance themselves from perceived failures. To match leadership between individuals or institutions and outcomes it is therefore crucial to map original intent: this requires not just an analysis of an actor's retrospective intent, but a historiographical tracing of their key positions and actions, partnerships and alliances with regard to a specific health outcome.

3. *Context*: Leadership is subject to the context in which it takes place. The political, social, economic and temporal context defines how leadership operates and how (and whether) it produces specific outcomes. Take two examples. First a leader that mobilises resources for health concern X in a time of economic boom may be seen as an effective leader in resource mobilisation, whereas a leader that fails to generate income or protect jobs in a specific sector during a time of economic austerity may be seen as a failure. Second a leader wants to roll out vaccination against disease Y. However, the community in which they work distrust the vaccine and the vaccinators, a thought echoed by the opposition government of the time. A leader who is successful in implementing the programme and mobilising support for it may be seen as effective in generating a beneficial output for global health. A leader who decides that this is not what the community wants and uses the resources for other health endeavours may also be seen as effective for responding to the community's wants and the political context of the country even though the public health objective has not been met. In both examples, the leaders can be labelled 'effective' or not depending on the context in which

they work and who does the labelling. Therefore in each scenario of analysing leadership, context determines what is seen as effective/successful and by whom as well as who is deemed ineffective and why.

Context also shapes explanations as to why a leader may be hidden. A leader may be hidden because they happen to operate at a level that means they go unnoticed. However, they may be deliberately hidden because of the context in which they are working. To be a leader, of course, means being visible – at least to the audience one is trying to persuade. Yet some leaders may deliberately hide from certain parts of society (such as their government) so as to maintain the work that they do or protect the interests of the community they serve. For example, a leader in Polio vaccination in Karachi, Pakistan may deliberately be hidden from groups that distrust and target vaccination workers but may still display a leadership role in mobilising workers and support among other key constituencies within the area. Hence context is not only about outcomes but is also about why a specific leader is hidden and whether their desire is to remain hidden. This is important to both how we understand leadership in global health but also how we design methodologies (and how we publish findings) that are sensitive to the contextual constraints and opportunities to such leadership.

4. *Form.* Form is perhaps the area in which most studies of leadership cluster, often with regard to how to be a better leader. For our purposes, form should not reveal how to do or improve leadership but necessitates a focus on the different types, skills and mechanisms of leadership used at multiple levels. As noted above, Young identified a number of different forms of leadership (structural, entrepreneurial and intellectual). Better understanding of which form of leadership particular leaders use, and which are influential in particular governance processes, could shed significant light on the way in which things 'get done' in global health governance, and on which sources and techniques are particularly influential within this governance arena. A focus on the form of leadership exhibited by hidden leaders is once again of crucial importance here; leadership means different things to different people and is context specific, thus the form leadership takes should be shaped to these contexts and positions. It is hidden forms of leadership and the context in which such leadership takes place that is often overlooked or ignored yet hold the most revealing insight into how global health policies work or fail.

5. *Outcome.* The final part of the matrix for analysing leadership is to trace the contribution of the leader to a particular political outcome. Outcomes can be a failed, partial or full realisation of intent. Although we present outcomes last (as it would be in the chronological exercise of leadership) in practice this may be the starting point for research into a particular case study, with an outcome representing a point from which to trace back the identity/positionality, intent, context and form of leadership involved in producing that outcome.

CONCLUSION

Global health governance is marked by an abundance of agents. However, what is frequently lacking in the current understanding of governance processes in global health is how individual agency impacts (and translates into) governance outcomes – raising such questions as who is exercising leadership; why; how; where; and with what effects. This paper has argued for a more holistic examination of the role of leadership in influencing a group of agents to come together in pursuit of common global health goals. This, it seems to us, is crucial to understanding how things 'get done' (and why they don't) in a governance context as diverse and uncoordinated as that which we see in global health. Important in this is the investigation of the leadership that is happening beyond the (western) hubs of global health activity.

A focus on leadership at multiple levels and different contexts matters for three reasons. First locating leadership beyond the global health hubs of presumed decision-making we can begin to fully globalise global health by expanding our critical lens to account for the individual agents mobilising political will and support for a number of different global health outcomes that are unseen when taking a more narrowly 'global' – i.e. institutional - perspective. Second, a focus on hidden leaders enhances understanding of the challenges, limits and opportunities to the delivery, and local formation of a number of global health priorities and how such agency can undermine, reshape, or heighten specific health outcomes. In other words, we can begin to unravel how things get done both within and beyond the elite in global health. Finally, consideration of hidden leaders will help identify any mismatch between context and intent in global health policy. In this regard context is the most challenging and central component of the five point matrix for leadership outlined in this paper.

We propose that any account of leadership has to be drawn from a full understanding of agency that transcends the idea that states and institutions (predominantly western based states and institutions) are the agents of global governance, to account for individual intent and action that is position- and context-specific. In doing so, studies on global health can begin to take fuller account of the hidden leaders that in practice exhibit considerable leverage and leadership in global health. Frequently it is these hidden leaders that get things done, subvert or enact wider forms of leadership and that reinforce or challenge ideas of what the global health agenda should look like. But whilst such a broad view of agency in global health governance seems normatively desirable, it does pose challenges for researchers. This paper has proposed an analytical framework for understanding leadership based on five points of analysis: i) identity/positionality; ii) intent; iii) form; iv); context and v) outcome as a basis to address such challenges.

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How "Global" is "Global Health"?
Examining the Geographical Diversity of Global Health Thinkers

Tess van der Rijt and Tikki Pang

Many health issues are transnational in nature and cannot be contained within national borders. Global health is therefore an area of study and research that should involve the collective opinions and ideas of diverse global health thinkers. This paper poses the question: how "global" is "global health"? Through an analysis of four different contributors shaping global health, including academics, journals, health institutions and presenters at global health conferences, this paper aims to determine if the development of global health is truly global. The paper concludes that global health is not being shaped by those who are most affected by it; the majority of people influencing and defining global health priorities represent institutions based in the developed world. A number of trends and opportunities are identified and recommendations are made to ameliorate the observed imbalance.

BACKGROUND

Due to globalization, urbanization, and increasing international travel and trade, global health is more relevant than ever. Health issues are oblivious to sovereign states and their individual health policies; they are transnational and can rapidly affect multiple countries. As stated by WHO Director-General Dr. Margaret Chan: "In our mobile, interdependent and interconnected world, threats arising from emerging and epidemic-prone diseases affect all countries. They reinforce our need for shared responsibility and collective action in the face of universal vulnerability…"[1]

Global health assistance is a multibillion-dollar industry. Between 1990 and 2011, funding of development assistance for health rose from U.S. $5.82 billion to U.S. $27.73 billion (Figure 1).[2] The Bill and Melinda Gates Foundation alone spent U.S. $8.95 billion on global health grants between January 1998 and December 2007.[3] In 2007, the amount spent by the Gates Foundation on global health was almost as much as WHO's annual budget (approximately U.S. $1.65 billion). Arguably, global health thinkers may have a strong influence over the priorities of these global health organizations, and the research, publications and presentations of these thinkers may impact upon such organizations' resource allocation decisions. As the global health industry affects health worldwide, especially populations living in the developing world, thinkers themselves should also be geographically dispersed to ensure that a diverse range of attitudes and experiences shape global health, rather than the perspectives of a select, privileged few. But are contributions to global health truly global, or are people shaping the concepts and ideas of global health predominantly from the developed world? This paper aims to address this issue by asking the question: "How global is global health?"

Figure 1: Development Assistance for Health 1990-2011. Source: Institute for Health Metrics and Evaluation, "Financing Global Health 2011: Continued Growth as MDG Deadline Approaches." Seattle: University of Washington, 2011.
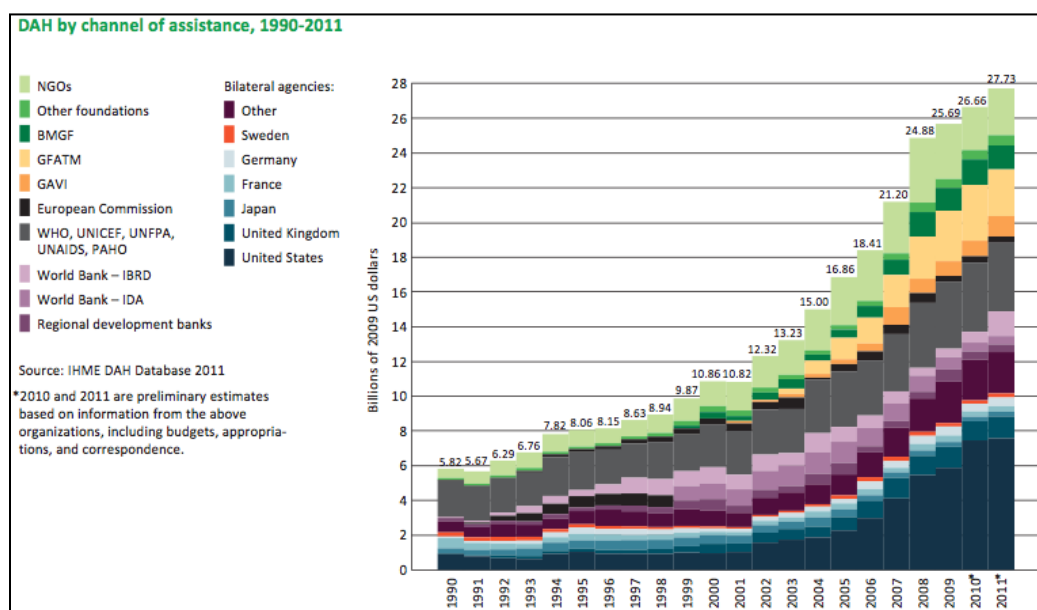
DEFINITIONS

Global Health

Although consensus on a definition of global health is yet to be obtained, key underlying concepts of what global health constitutes have emerged. In 2009, Koplan et al. called for a common definition of global health.[4] In the paper, Koplan et al. consider various definitions previously proposed and accordingly propose their own definition:

> "Global health is an area for study, research and practice that places a priority on improving health and achieving equity in health for all people worldwide. Global health emphasizes transnational health issues, determinants, and solutions; involves many disciplines within and beyond the health sciences and promotes interdisciplinary collaboration; and is a synthesis of population-based prevention with individual-level clinical care."[5]

Since the publication of Koplan et al's paper, new ideas and issues have become apparent, including those outlined by Bozorgmehr's work.[6] Bozorgmehr questions the "global" in "global health," and argues that the global-as-supraterritorial provides "new" objects for research, education and practice while avoiding redundancy. Nevertheless, for the purposes of this paper, Koplan's definition will be observed.

Global Health Articles

For the purposes of this study, a "global health article" is defined as an article that has the phrase "global health" in either its title or abstract and is available on PubMed. In this sense, it is an article that has the subject of global health at its core.

Global Health Journals

A "global health journal" is a journal that publishes articles on global health and is found within the PubMed database. While global health may not be the central issue of the journal, it publishes articles on the subject.

Global Health Institutions

A "global health institution" is any institute, department, school, program, college or center that engages in the research, training, policy-making or education of global health. If it is an educational institution, with global health being one of the core components in its offered curriculum.

Global Health Conferences

There is a vast array of conferences that discuss issues pertaining to global health; however, this article chose a select few based on their global reputation and coverage, budget and number of participants. Each of the conferences listed focus on global health issues. While the International Association of Public Health Institutes (IANPHI) is an association of public health institutes, rather than global health institutes, it was included as it is a global initiative that develops coordinated public health systems, resulting in a global discussion on health systems.

AIM

To explore and determine whether the shaping of ideas and concepts around global health is truly occurring globally, within both developed and developing countries, or if it is being shaped primarily by leaders and academics in the developed world.

METHOD

In order to determine how "global" the field of global health is, four different areas that potentially contribute to the shaping of global health and the sharing of ideas were examined as proxy indicators: the authors of global health articles; the journals publishing articles on global health; the health institutions engaging in global health research and training; and the presenters at major "global health" conferences.

CAVEAT

An important limitation of this paper is that the origin of the academics and presenters used in this study is based on the location of the institution they represent and not their

nationality. Many citizens of developing countries work for institutions in the developed world and their presence in these organizations can effectively influence decision-making, giving additional perspective and voice to developing country issues. Therefore it must be taken into consideration that developing country thinkers may be influencing the shaping of global health from within developed country institutions.

How Geographically Diverse are Authors Publishing Articles on Global Health?

To effectively obtain a sample of articles on global health and, in turn, research the authors of these articles, the term 'global health' was searched in PubMed (http://www.ncbi.nlm.nih.gov/pubmed). The first 100 results were analyzed. The institution that the author(s) represented and the country where the institution is based were noted. The number of authors contributing to each article was also recorded. If the article was a collaboration of authors of institutions from differing countries, the institution that the first author represented was listed separately.

How Geographically Diverse are Journals Publishing Articles on Global Health?

As global health intersects numerous disciplines, there are a large number of journals publishing articles on global health. These include journals on the environment and climate change, foreign policy, international trade, clinical medicine, public policy, aid, and development. It was only possible to examine a sample of journals publishing articles on global health. The term "global health" was searched in PubMed and the top 100 search results of each were utilized for this study. Information on where the journal was based was found under the title "country of publication" of the journal, as provided through PubMed.

How Geographically Diverse are Health Institutions Engaging in Global Health Research and Training?

Three different databases were explored to obtain a comprehensive list of health institutions engaging in health research and training. These included: The Consortium of Universities for Global Health (www.cugh.org), which provided a wide-ranging list of health institutions engaged in global health in the USA and Canada; The TropEd Network (www.troped.org), which provided a thorough list of health institutes in Europe and some in Asia; and, www.healthtraining.org, the most comprehensive and extensive database that included many institutions outside of North America and Europe. If it was unclear from the name of the institution whether or not they are engaged in global health, further research into the institution was conducted, including researching directly from the institution's website. Interestingly, none of the three search engines listed any health institutes in China. Therefore these were added separately, having obtained the information through key informants.[7]

How Geographically Diverse are the Presenters at Global Health Conferences?

Through a simple Google search of the term "global health conference", it is evident that there are numerous conferences worldwide that discuss and promote global health. For the purposes of this study, seven major global health conferences hosted by

international organizations were examined and analyzed. In addition, a small sample of regional and national global health conferences, which will contribute to the overall discussion, were studied. The list of speakers at each conference was found on each of the organization's individual websites. If not already apparent from the information provided on the website, further research was carried out to find out which institution the presenter represented and in which country the institution is based.

RESULTS

How Geographically Diverse are Authors Writing Articles on Global Health?

From the sample analysis (Figure 2), the majority of authors writing on global health originate from institutions in the developed world. 656 authors contributed to the 100 articles used in this sample study. The graph shows the origin of 533 of those authors (the 123 authors who contributed to articles that were a collaboration of authors from institutions in differing countries were not included in Figure 2, as it was sometimes unclear which institution each author represented). Seventy-seven percent (411 of 533) of authors came from the developed world (including Western Europe, USA, Canada, Australia and New Zealand). Of the lesser-developed regions, the Asia Pacific was most strongly represented, with 14% (77 of 533) from this region. Within the Asia Pacific region, authors originated from institutions in China, Indonesia, Japan, Nepal and India, with the two largest percentages from Nepal (38%) and China (30%). Nepal's percentage is high because although authors from Nepalese institutions only wrote two articles, 29 authors contributed to the two articles. From the African region, authors represented institutions in Kenya, Egypt and South Africa. In the Middle East, authors were from institutions in Kuwait and Iran. Interestingly, no authors originated from the Central/South American region. All nine authors in Eastern Europe wrote from institutions in Macedonia and all of these authors contributed to one article. According to the World Bank, of the 24 countries represented in Figure 2, all are high-income or upper-middle income countries, except Indonesia and India, which are lower-middle income countries and Kenya and Nepal, which are classified as low-income countries.[8]

Figure 2: Geographical diversity of authors writing articles on global health
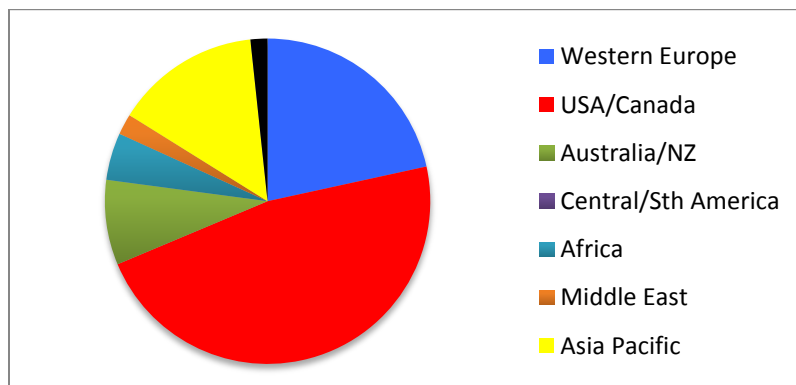
Figure 3 displays the origin of the first author of each of the 100 articles used in the study. Again, it is evident that the vast majority of first authors (80%) are from the developed world. From regions with a majority of middle-income/developing countries, Asia Pacific authors produced the greatest number of articles (13%).

Figure 3: Geographical diversity of first author of global health articles
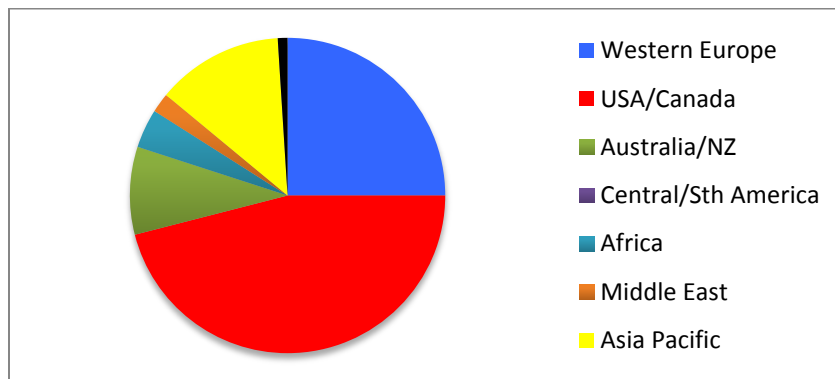
*Collaborations of Institutions from Different Countries*

Twelve % of the articles are collaborations of authors from institutions in different countries. Of these 12 collaborated articles, eight articles were written by authors based in institutions in upper-middle income and high-income countries and three of these articles were written by authors based in different regions in the world. Four articles were written by authors based in institutions in a mix of high-income, lower-middle income and/or low-income countries. No articles involved collaboration by authors based in only lower-middle income and/or low-income countries – there was at least one author contributing to each of the collaborated articles that represented an institution based in a high-income country. As such, and based on this small sample, there was only north-south collaboration and no evidence of south-south collaboration.

How Geographically Diverse are Journals Publishing Articles on Global Health?

Ninety-three percent (126 of 135) of journals publishing articles on global health are in the developed world (Figure 4). Fifty percent originate from England and Western Europe and 41% from the USA and Canada. Only 2% originate in Australia and New Zealand.

Of the lesser developed regions, the Asia Pacific produces the largest number of journals publishing articles on global health, with two being published in China and one each in both Thailand and India. In the other regions, journals are being published in Brazil, Egypt, Israel, Russia and Turkey, all of which are high-income or upper-middle income countries, except Egypt, which is classified as a lower-middle income country.

Figure 4: Geographical diversity of journals publishing articles on global health
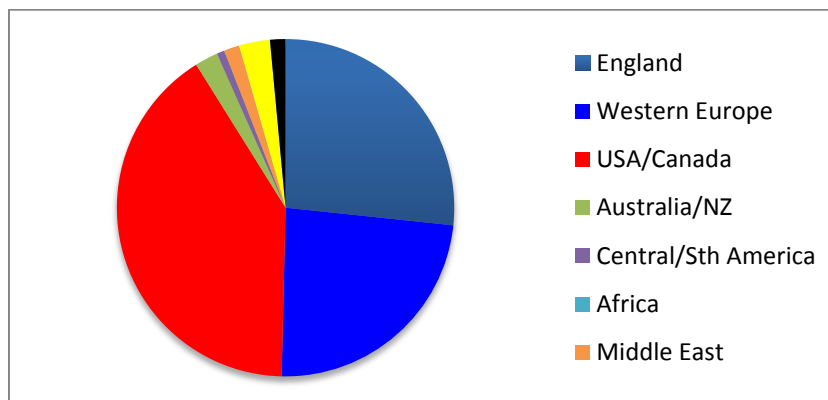
How Geographically Diverse are Health Institutions Engaging in Global Health Research and Training?

Seventy-two percent (183 of 252) of global health institutions identified in this study are based in the developed world (Figure 5). Although this percentage represents the majority, there is greater regional diversity compared to the results in previous sections.. Twelve percent (31 of 252) of global health institutions are in the Asia Pacific (not including Australia and New Zealand) and are based in 13 different countries, including Singapore, Japan, Malaysia, Thailand, Taiwan, India, Fiji, Korea, Bangladesh, Hawaii, Pakistan, China and the Philippines. Of these countries, four are classified as lower-income countries (India, Fiji, Pakistan and Philippines) and one is classified as a low-income country (Bangladesh).

Figure 5: Geographical diversity of global health institutions
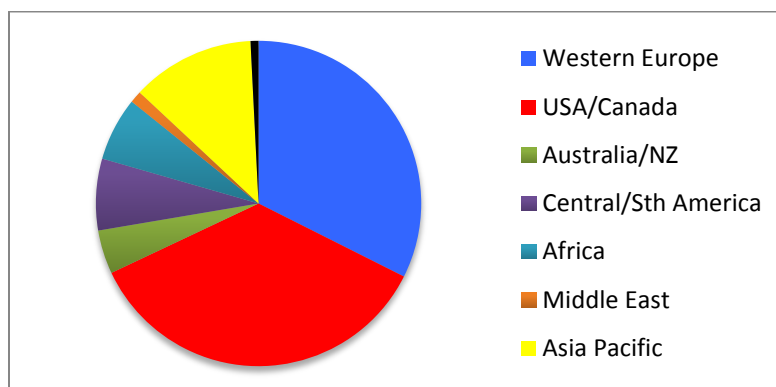
The same geographical diversity is also evident in Central and South America, where 18 institutions (7%) are found throughout Chile, Argentina, Brazil, Cuba, Mexico, Guatemala, Colombia, Peru and Jamaica (all of which are classified as upper-middle income countries, except Guatemala which is considered a lower-middle income country). In Africa, there are 16 global health institutions in Uganda, South Africa, Tanzania, Kenya, Zimbabwe, Ghana and Egypt. Two of these seven African countries are classified as lower-

middle income countries and four are classified as low-income countries. Two global health institutions are located in Eastern Europe (Russia and Hungary) and three institutions in the Middle East (Israel).

*How Geographically Diverse are the Presenters at Global Health Conferences?*

Global health conferences hosted by international organizations: seven global health conferences hosted by international organizations were examined; the World Health Summit, the International Association of Public Health Institutes (IANPHI), the Global Health Council, the Global Forum for Health Research, the Pacific Health Summit, the Second Global Symposium on Health Systems Research, and the World Conference on Social Determinants of Health.

World Health Summit:

The World Health Summit is the annual conference of the M8 Alliance of Academic Health Centers and Medical Universities, organized by Charité Universitätsmedizin Berlin in collaboration with the National Academies of Sciences.[9] Since 2009, four such conferences have been held.

The World Health Summits support the assertion that academics and institutions from developed countries dominate the shaping of global health ideas. The majority of presenters at the Summits from 2009 – 2012 represented institutions based in Western Europe and in the USA (Figure 6). From 2009 – 2012 the Summit was hosted in Berlin, Germany and consequently many presenters represented German institutions. In 2009, 2010 and 2011, 39%, 20% and 22% consecutively of presenters at the summits spoke on behalf of German institutions. Between 137 and 319 people presented at the 2009, 2010 and 2011 summits, while only 24 people presented at the 2012 summits. At the 2012 summit, 12.5% of presenters came from German institutions and 83% of speakers represented institutions in the developed world. Throughout the four summits, Asia Pacific and Africa have been the most strongly represented lesser-developed world regions.

Figure 6: World Health Summit presenters 2009 – 2010 – 2011 – 2012
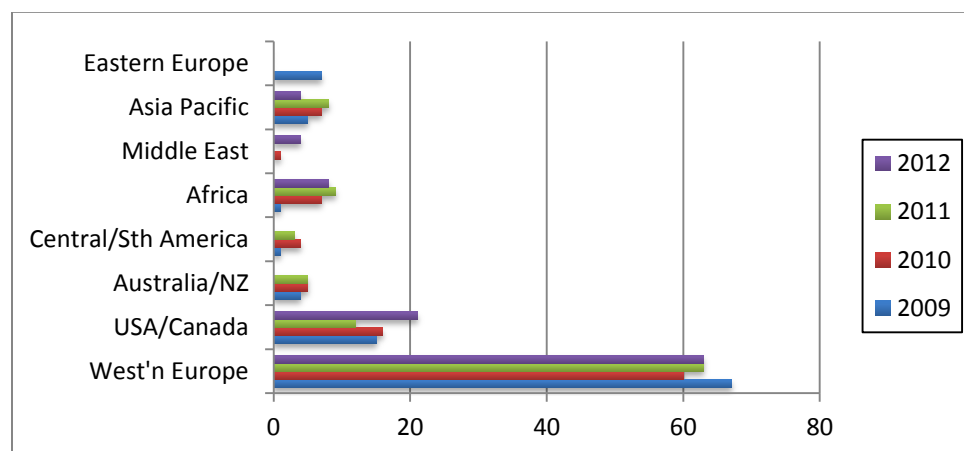
*International Association of National Public Health Institutes:*

The IANPHI is a global initiative that aims to develop stronger and more coordinated public health systems through the development and support of national public health institutes.[10] The IANPHI has 79 members that represent the public health institutes of the world. It is important to note that only members of the IANPHI can attend and address the annual conferences. There are no health institutes in Australia or New Zealand that are members of the IANPHI and therefore they are not represented and there are a limited number of IANPHI member health institutes in Eastern Europe.

In contrast to the World Health Summit, IANPHI conferences are much more inclusive and representative of the world's regions (Figure 7). The world regions that have IANPHI member institutes are well represented and the majority of speakers at the 2009, 2010 and 2011 conferences came from institutions in the lesser-developed world regions.

Interestingly there was a change in the origin of speakers at the 2012 conference, with much less regional diversity and nearly half the number of speakers compared to 2010 and 2011. The 2012 IANPHI conference was held in Mexico City and accordingly many of the speakers came from Mexican institutions (35%, 8 of 23). The developed regions of Western Europe (26%, 6 of 23) and USA/Canada (31%, 7 of 23) were also well represented. Only one presenter each represented the regions of Asia Pacific and Africa.

In analyzing the IANPHI conference presenters from 2009 – 2012, it was observed that the location of the conference affects the origin of presenters. In 2009 the conference was held in South Africa and subsequently there was a rise in presenters from the African region. There was a rise in American presenters in 2010 (the conference was hosted in the USA), a rise in presenters from Europe in 2011 (the conference was hosted in Finland) and a rise in presenters in 2012 from Central/South America (when the conference was hosted in Mexico).

Figure 7: IANPHI conference presenters 2009-2010-2011-2012
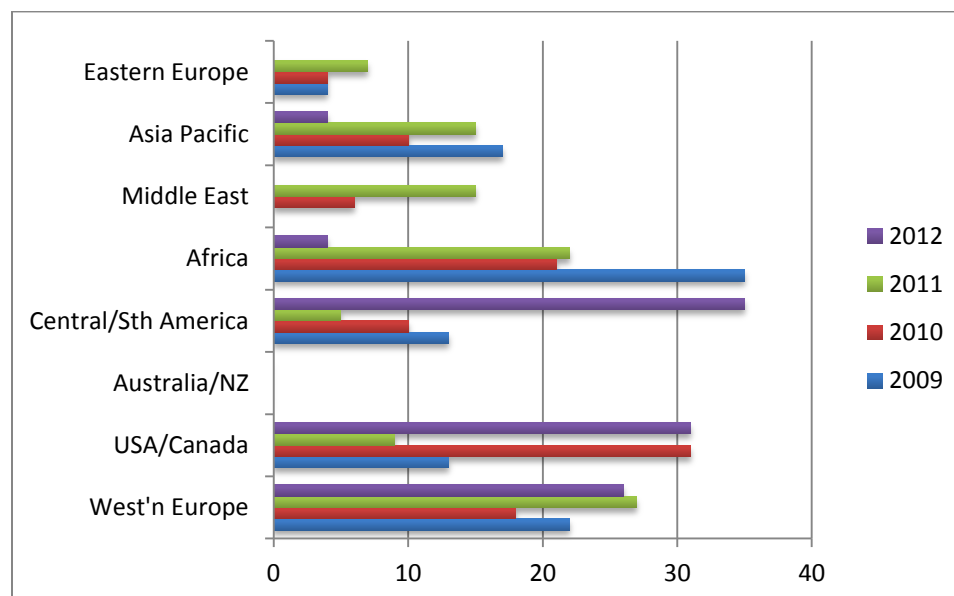
Even though the conference location influenced the origin of presenters at the conferences, the presenters strongly represented different regions, particularly at the 2010 and 2011 conference. For example, the 2011 conference was hosted in Helsinki, Finland but 64% of speakers came from the regions of the world dominated by low income and lower-middle income countries. Various countries within regions were also well represented, with African institutions constituting 22% of speakers (9 of 41) and speakers hailing from institutions in Nigeria, Morocco, Ghana, Tanzania, Mozambique and Guinea Bissau. From Central/South America, Mexico and Brazil were represented. From the Middle East, Iran, Egypt, Israel and Afghanistan institutions were represented and Serbian, Russian and Slovenian institutions represented the region of Eastern Europe. At the 2010 conference, the greatest represented lesser-developed region was Africa, with 21% of speakers (10 of 49) coming from institutions in Ethiopia, Tanzania, Morocco, Nigeria, Mozambique and Guinea-Bissau. Only 23 people presented at the 2009 conference, but nonetheless there was a breadth of speakers from regions in Western Europe, USA and Canada, Central and South America, Africa and the Asia Pacific.

Global Health Council:

The Global Health Council was the world's largest and most diverse membership alliance dedicated to improving the health of the 2 billion people who live on less than $2 a day. [11] Although the Council was dissolved in June 2012, its past conferences are still relevant to this study and have therefore been included.

Presenters from institutions in the developed world markedly dominate Global Health Council conferences. Of the 23 presenters at the 2011 Global Health Council conference, 13 (56%) came from US institutions (Figure 8). Otherwise, of the regions represented, it was more or less evenly dispersed, with two from Western Europe, three from Central/South America, three from Africa and two from the Asia Pacific. There were no representatives from Australia/New Zealand or the Middle East.

Throughout the 2009, 2010 and 2011 Global Health Council conferences, presenters from USA dominated the conferences, followed by those in Western Europe (Figure 8). Of the lesser-developed regions, Africa was most strongly represented, with a rise in representatives from the Asia Pacific in 2011. Institutions from the Middle East and Eastern Europe were poorly represented. At the 2010 conference, 76 people presented at the conference and 48 of these (63%) came from institutions in the USA and Canada. Twenty-four percent (18 of 76) came from Western European institutions, resulting in over 87% of speakers representing institutions in developed countries. Only 13% of speakers came from developing country institutions, only representing the African and Central/South American regions. Presenters represented institutions in Mexico, Argentina, Haiti, Zambia, Uganda, Botswana and Nigeria.

In 2009, although 73% of presenters (24 of 33) represented institutions in the developed country regions of Western Europe and the USA, the origin of presenters in other regions was diverse. Six presenters represented African institutions in Ghana, Senegal, Sierra Leone, South Africa, Uganda and Kenya. There was also one speaker from each of the regions of the Middle East, Asia Pacific and South America.

Figure 8: Global Health Council presenters 2009-2010-2011
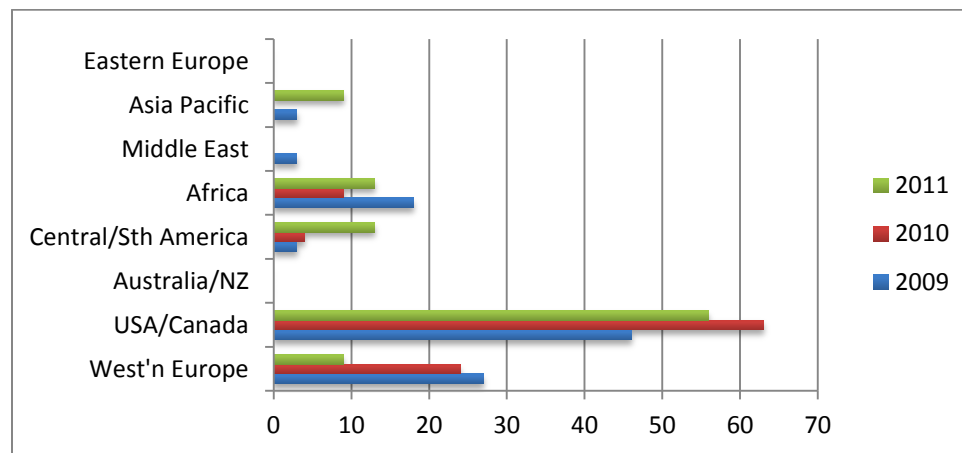
Global Forum for Health Research:

The Global Forum for Health Research is part of The COHRED Group, a non-governmental organization committed to research and innovation for health.[12] The forum merged into COHRED in 2010 and consequently has undergone significant reform that has altered its objectives and leadership. In 2009 the Global Forum decided to hold conferences biennially rather than annually. However, the 2011 conference did not occur as the Forum dissolved and merged into the Council on Health Research for Development (COHRED). Therefore the Forum following the 2009 Forum was delayed until April 2012. It was not possible to obtain information on the 2008 and 2007 forums and as such this paper analyses the 2012, 2009, 2006 and 2005 forums.

The 2012 conference was held in South Africa and consequently many presenters represented African institutions (Figure 9). 42% of speakers (24 of 57) came from institutions in Africa, representing organizations in South Africa, Kenya, Burkina Faso, Tanzania, Senegal, Botswana, Ethiopia, Cameroon, Uganda and Tunisia. The same number of speakers (42%) came from the developed regions of Western Europe and the USA. After Africa, the next best-represented, lesser-developed region was Central/South America, with six speakers (10%) originating from institutions in Mexico, Colombia, Argentina, Panama and Chile. There were also two speakers from the Philippines and one speaker from Lebanon.

The 2009 Forum hosted in Uruguay consisted of a majority of speakers (53%, 20 of 38) from the developed regions of USA/Canada, Western Europe and Australia/New Zealand. Of the lesser-developed regions, Central/South America was best represented, with 21% of speakers (8 of 38) coming from institutions in this region. The next most strongly represented lesser-developed region was Asia Pacific, with 13% of speakers (5 of 38).

The 2006 and 2005 forums were much larger forums compared to 2009 and 2012, with 233 and 256 presenters consecutively. At both of these forums, the majority of presenters came from lesser-developed regions. At the 2006 forum, 40% of presenters (93 of 233) came from Western Europe, USA/Canada, Australia/New Zealand and 42% of presenters (108 of 256) at the 2005 forum came from these regions. The most strongly represented lesser-developed region was dependent upon where the forum was hosted. The

2005 forum was held in Egypt and subsequently 26% of presenters (61 of 233) came from African institutions. The next best-represented lesser-developed region was Asia Pacific, with 16% of presenters (37 of 233) from this region. The 2005 forum was hosted in India and the greatest region represented was the Asia Pacific, with 36% of presenters (91 of 256). Africa also had a fairly strong representation, with 11% of presenters (29 of 256) coming from this region. Of these lesser-developed regions, Asia Pacific and Africa were the most strongly represented regions in these two forums.

Figure 9: Global Forum for Health Research presenters 2005-2006-2009-2012
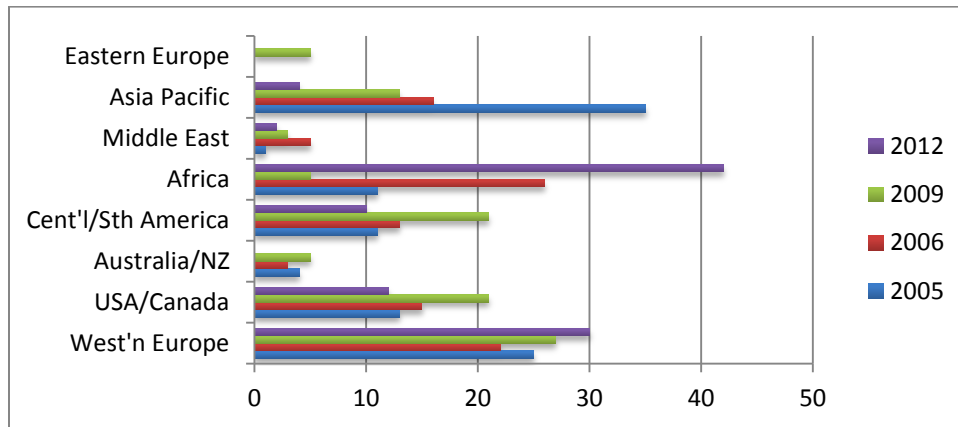
Pacific Health Summit:

Since its inception in 2005, the Summit's mission has been to connect science, industry and policy for a healthier world. Hosted in either London or Seattle, the 2009 – 2012 conferences were markedly dominated by presenters from the USA and Western Europe (Figure 10). Of the lesser-developed regions, the Asia Pacific is the most strongly represented, with Chinese and Indian institutions continually being the most strongly represented. For example in 2012, 50% (5 of 10) institutions from the Asia Pacific were from China and 40% (4 of 10) were from India. Institutions from South Africa were the most strongly represented within the African region.

Figure 10: Pacific Health Summit presenters 2009-2010-2011-2012
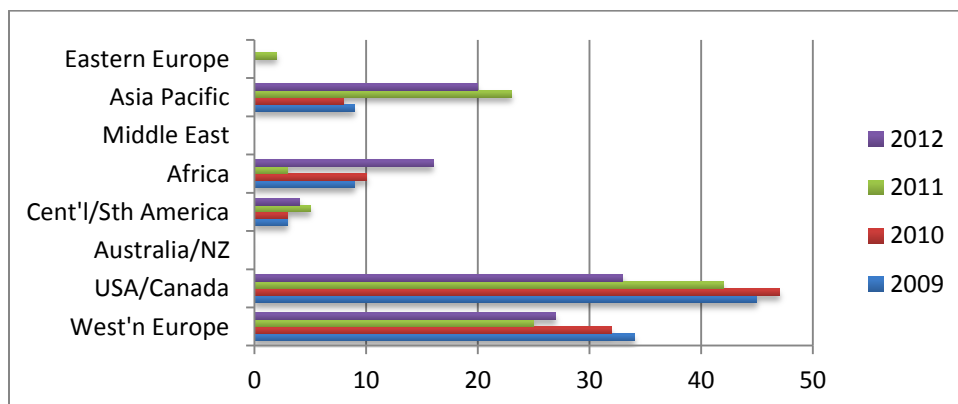
Global Symposium on Health Systems Research:

The Global Symposium is dedicated to evaluating progress, sharing insights and recalibrating the agenda of science to accelerate universal health coverage. The Second Symposium in 2012 was hosted in Beijing, China and 50% of presenters represented institutions in the developed world (Figure 11). In particular, they represented institutions from the United States of America and the United Kingdom. Otherwise every region in the world was represented, with a large majority of presenters from the Asia Pacific. 28% (209 of 740) of presenters hailed from this region, with 32% (67 of 209) of the region's representatives coming from Chinese institutions and 20% (42 of 209) from Indian institutions. Another 15 Asia Pacific countries were represented at the conference. The African region was also fairly represented, with 15% (115 of 740) of presenters at the Symposium from this region. Institutions from Ghana (21%, 24 of 115) and South Africa (19%, 22 of 115) were most strongly represented.

Figure 11: Global Symposium on Health Systems Research 2012

2011 World Conference on Social Determinants of Health:
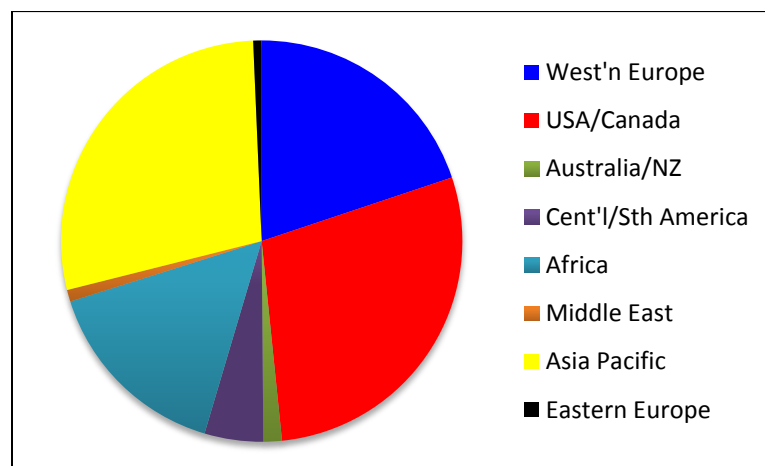
The World Conference on Social Determinants of Health was convened by the WHO and was hosted in Rio de Janeiro, Brazil in October, 2011. It aimed to build support for the implementation of action on social determinants of health. The conference brought together over 1000 participants representing 125 Member States and a diverse group of stakeholders.[13] The conference ended with the adoption of a Rio Political Declaration.

The conference was hosted in Brazil and convened by the WHO, therefore the greatest number of represented institutions were from Brazil (14 of 96, 15%) and Switzerland (17 of 96, 18%) (Figure 12). Nonetheless, other regions and countries were still well represented, with speakers from every region in the world representing institutions in 39 different countries. Ten percent of speakers came from the Asia Pacific and represented institutions in seven different countries, while another 10% came from Africa and represented institutions in six different countries. Three Eastern European institutions were represented and one from the Middle East.

Figure 12: 2011 World Conference on Social Determinants of Health presenters
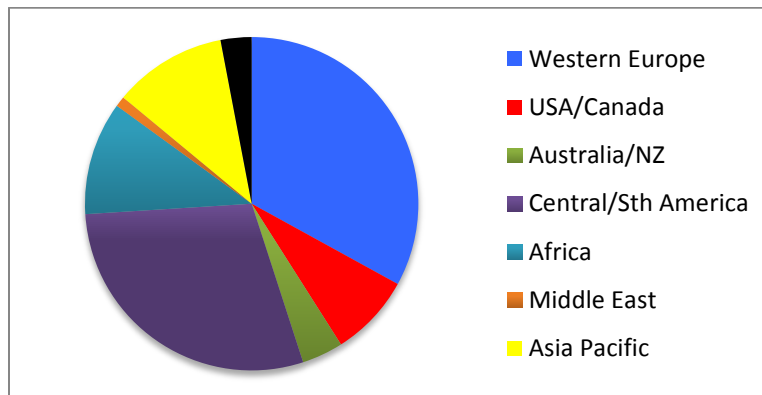
Global health conferences hosted by national/regional organizations: This paper examined a sample of global health conferences hosted by regional and national organizations. It became evident that the presenters tended to represent institutions that are based in the same country as the conference's host organization and subsequently where the conference was held. For example, at the Australian Medical Students' Association Global Health Conference, 95% of presenters represented Australian institutions. The Western Regional International Health Conference, convened by medical students at the University of Washington, only had US/Canadian speakers address their conference. Sixty percent of presenters (3 of 5) at the 2005 Pacific Global Health Conference came from institutions in the Pacific.

The Consortium of Universities for Global Health (CUGH) was examined individually as its annual meeting "has become the world's leading academic global health conference... the number of registered attendees has grown to more than 1,400 from 62 countries and includes more than 500 students."[14] The vast majority of presenters at the CUGH meetings from 2009 - 2013 came from US and Canadian institutions, with 79% of presenters (25 of 34) in 2013, 82% of presenters (141 of 171) in 2011, 79% of presenters (76 of 97) in 2010 and 94% (48 of 51) in 2009 from these two countries alone (Figure 13). The few other presenters generally represented institutions in Africa, Western Europe, Central/South America and only a few from the Asia Pacific.

Figure 13: Consortium of Universities for Global Health 2009-2010-2011-2013
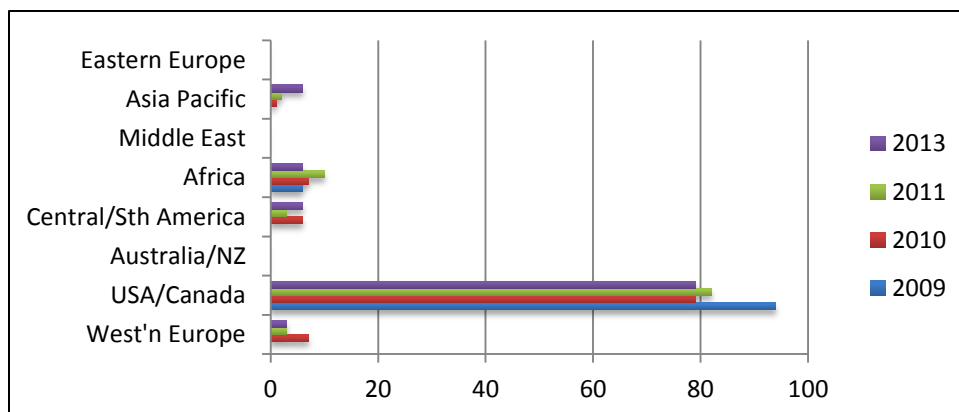
DISCUSSION

The results of this study support the contention that global health is shaped primarily by those in the developed world, which in turn may potentially influence the priorities of the major donors of global health initiatives.

Overall Context

The unprecedented amount of resources being disbursed as health development aid by many diverse organizations in the developed world (see Figure 1) are focused primarily on improving health outcomes in the developing countries. This is true for the three major agencies among these global health initiatives: the Global Fund for Combating HIV/AIDS, TB and Malaria; the Global Alliance for Vaccines and Immunization (GAVI); and the President's Emergency Plan for AIDS Relief (PEPFAR). Overall, up to 10.2% of health expenditure in the African region comes from external sources, with Malawi and Eritrea depending on external aid for 80% and 62% of their national health budgets respectively.[15] In the Pacific region, 69% of Micronesia's health budget, and 61% of Niue's, comes from external sources. In Estonia, this figure is 63%.
In the context of the ongoing economic and financial crisis in the developed world, these countries may suffer unwanted consequences on their health care delivery systems. Given these observations and realities it would stand to reason that the shaping of ideas around global health, as well as implementation processes, should be an inclusive and equitable process involving all key stakeholders, especially from countries in the developing world who are the recipients of aid from global health initiatives.

Observations of Results

There are some important considerations and observations that were made during this study. Although the majority of authors writing articles on global health and the majority of journals publishing articles on global health are in the developed world, there are logical reasons for these results. As there are more health institutions in developed countries, there is a preponderance of academics in developed countries who subsequently publish a high number of articles on global health. Lack of funding and resources are obvious limitations to journals being published in developing countries are funding and resources. Therefore it is only through an increase in funding to support and create more institutions and journals in the lesser-developed regions that this gap may be rectified.
When examining the origin of presenters at global health conferences, a trend became evident wherein the speakers tended to represent institutions that are based in the same country as where the conference was held. Although also evident in the conferences hosted by international organizations, the trend is even more prevalent with the regional/national conferences. This is presumably because the regional/national conferences have smaller budgets and cannot afford to pay for international presenters. Conferences are also an opportunity to promote the thinkers and the progress within the host country. The trend was prevalent within the World Health Summit, with a large percentage of presenters representing German institutions, the country where the summit has been hosted every year. Of the sample study of global health conferences, the conference that displayed the greatest global representation of presenters was the World

Conference on Social Determinants of Health. Perhaps the WHO, the convener of the conference, took affirmative action to ensure that a variety of perspectives and experiences were heard from every region in the world. Nonetheless it is evidence that with a reasonable budget, geographical diversity of presenters is feasible.

The Asia Pacific: An Important Region for Global Health

Although the results depicted global health ideas and frameworks as being shaped by those in the developed world, the importance of the Asia Pacific region was also recognized. When examining the lesser-developed regions of the world, namely Africa, Asia Pacific, Central and South America, the Middle East and Eastern Europe, it became evident that compared to the other regions listed, the Asia Pacific was generally well represented. When examining the origin of authors writing articles on global health, the Asia Pacific was the most strongly represented lesser-developed region, with 14% of authors from this region of the world. Authors from the Asia-Pacific composed 63% of authors writing from institutions in the lesser-developed regions.

Results were similar when examining the diversity of journals publishing articles on global health. Although lesser-developed regions comprise only 7% of journals in the study, the Asia Pacific region produces the greatest number, with 44% (4 of 9) of journals in the lesser-developed regions of the Asia Pacific. The Asia Pacific also has the greatest number of global health institutions of the lesser-developed regions, with 12% of institutions in this region (45% of institutions in the lesser-developed regions) in 13 different countries. The diversity of countries in the Asia Pacific that hosted a global health institution was a positive finding, following on from parts one and two whereby the Asia Pacific was generally dominated by people representing Chinese and Indian institutions. There has also been an increase in presenters from the Asia-Pacific region at the World Health Summit and the Global Health Council conferences.

Therefore it appears that the Asia Pacific is becoming an important region concerning the shaping of global health agendas and priorities, and an essential counterbalance to the views of the USA and Western European countries. This is also evident by the fact that high-level conferences are increasingly being hosted in Asia, such as the 2009 International Scientific Symposium on Influenza Pandemic Response and Preparedness and the Global Symposium on Health Systems Research, both held in Beijing. The importance of the Asia Pacific region is consistent with literature examining global health governance in Asia, which outlines that developing Asia's share of global gross domestic product has tripled over the past three decades, growing from 8% in 1980 to 24% in 2010.[16] There may be opportunity for growth of global health within the region and for collaboration of institutions within the Asia Pacific and neighboring regions.

With regards to global health conferences, the rising importance of the Asia-Pacific is also reflected in the fact that the World Health Summit, which was analyzed in the present study, will hold its first ever regional meeting in Singapore in April 2013.

Regional Collaboration

The results also illustrated a potential opportunity for collaboration within regions. Of the 12 countries in lesser-developed regions that were represented in part one of this study (with regards to the authors of global health articles), eight of these countries were

upper-middle income or high-income countries. Of the 33 countries that host global health institutions in the lesser-developed regions of the world, 12 are lower-middle income or low-income countries. Authors and staff of institutions in high-income or upper-middle income countries should collaborate with colleagues in the lower-middle income and low-income countries in their region. This could result in a greater perspective of ideas and ensure that global health is shaped by a diversity of thinkers.

Future Considerations

There are areas of this study that could be developed and further explored. This paper analyzed 100 published academic articles on global health. It could be interesting to obtain additional information on the impact factors of these articles and how often they are cited by peers in the field. Likewise, it could be useful to explore which articles generally on the topic of global health are the most cited and the journals they are published in. Furthermore, it could be interesting to examine journal articles on global health not written in the English language. An increase of journals published in the lesser-developed regions would no doubt result in an increase in journals being published in languages other than English.

While this paper has examined the question "How global is global health?" from a primarily geographical perspective, two future areas of future research are worth considering. First, beyond the shaping of ideas and concepts of global health, an interesting question to pose could be "how global is global health governance?" Is global health governance and major global health initiatives perpetuating the findings in this paper and basing its decision-making and programmatic implementation on the perspectives of a select few, or is it more inclusive of developing country voices? A future study will examine if the governance of global health institutions also reveals geographic limitations and exclusivity. The study will explore this question through investigating the geographical diversity of global health non-governmental organizations working in global health, the geographical diversity of members of executive/ advisory/ governing boards of global health institutions and researching which Member States contribute to global health discussions at the World Health Assembly.

Beyond geographical diversity, what are the drivers and factors in the development of the ideas on global health more broadly? Are these ideas only driven by developed country and 'western' norms and values, or are there parallel and independent ideational concepts that are shaped by countries and regions in other parts of the world? For example, China and India are becoming increasingly important players in the global health development aid field, and the strategies and objectives of such aid seem different to those of Japan, for example.[17] A more in-depth study in this area would seem warranted to gain more insights on broader ideational contributions from various sources

Future Shaping of Ideas Through the Training of Health Professionals

When examining regional and national global health conferences, it was observed that student medical associations were active in convening these conferences. Is this evidence of an interest in global health beyond what is being offered in the universities' formal curriculum? Currently there are studies being undertaken in the UK that examine the national public health training programme and whether it adequately prepares its

graduates to operate in a globalized world.[18] The paper argues that global health issues are not being addressed by the current training curriculum or in the written examination, despite trainee interest in the subject. According to the findings, the UK needs to adapt its training programme to better reflect today's challenges.[19] Similar studies in other countries would be useful to examine and ensure that the new generation of doctors are prepared to face the challenges posed by global health issues.

CONCLUSION AND RECOMMENDATIONS

Institutions and thinkers in the developed world currently dominate the shaping of global health ideas and frameworks. This is an issue that must be rectified to ensure that those most affected by global health are contributing to it and influencing priority setting. Based on this study, some key recommendations were developed to remedy the imbalance and ensure that global health is truly global:

- Establish a more inclusive definition of global health to ensure a common understanding of the goals it seeks to achieve
- Journal editors publishing articles on global health should take affirmative action to ensure institutions in developing nations are better represented
- Global health journals should be established in developing countries
- Funding should be better channeled to support the development of additional global health institutions in developing countries to ensure sustainable long-term capacity building
- Staff and executives of global health institutions should encourage collaboration with institutions in their region and collaboration with institutions in lower-middle income and low-income countries. Institutions in this country income bracket should forge collaborations with upper-middle income and high-income countries in their region.
- International conferences should encourage and facilitate through funding greater participation from developing country researchers and academics. Researchers from developing countries should take a more proactive role in global debates
- Every medical school should have a global health component to its curriculum

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Acknowledgments

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Institutional Readiness in Practice of Pandemic Response to an Emerging Infectious Disease

Asif B. Farooq and Shannon E. Majowicz

This paper argues that emerging and re-emerging infectious diseases (EIDs) remain a threat-focused security issue as the relative success of recent international responses do not fully reflect our current readiness for EID outbreaks. Existing pandemic response plans have been tested only for either virulent or highly transmissible diseases. Therefore, global health institutions have not yet been tested for the worst-case scenario: a disease with high virulence and transmissibility. We categorize EIDs into four quartiles according to their virulence and transmissibility, identify five relevant factors, and use recent EID outbreaks to develop inferences for response capacity to a possible outbreak of highly virulent and transmissible EIDs. We conclude there may be significant shortcomings in the existing pandemic response capacity to EIDs, which could lead to a public health crisis.

INTRODUCTION

A pandemic from an emerging or re-emerging infectious disease (EID) is a threat-focused human security issue. EIDs, which can emerge at any time, pose such a risk in a variety of ways. With case fatality ratios (CFR) that can exceed 80%[1] as with Marburg virus, EIDs can be highly virulent with severe consequences, including death, if not contained on time. Even pathogens with a likely low CFR of 2-3% can cause millions of deaths if the strain is novel within a naïve population, like the influenza pandemic of 1918-1919.[2] An EID can be highly transmissible, enabling rapid and efficient global spread to different parts of the world. Even with low virulence, a highly transmissible EID can disrupt normal life and weaken a country's economy and security.[3] Mutations of the genetic make up of a responsible pathogen during a pandemic can potentially result in a deadlier strain.[4] As a result, outbreaks of EIDs are often unpredictable in terms of origin, time, characteristics and consequences. Given the unprecedented level of global connectivity, development of an effective pandemic response plan is a pivotal task of global health institutions.

In response to recent outbreaks of H5N1 influenza (2004-2013), Severe Acute Respiratory Syndrome (SARS) (2002-2003), H1N1 influenza (2009-2011), and Ebola and Marburg viruses (2000-2011),[5] institutional actors like the World Health Organization (WHO) and other regional and national actors developed response programs including state of the art surveillance systems such as Event Management System (EMS), Event Information Site (EIS), Global Influenza Surveillance Network (GISN) and also response systems under Global Outbreak Alert and Response Network (GOARN).[6] These global efforts are complimented by regional and national programs, such as the MeKong Basin Disease Surveillance (MBDS) in six countries (Cambodia, China, Lao PDR, Myanmar, Thailand and Vietnam), and government organizations such as the Centers for Disease Control and Prevention (CDC) in the United States (U.S.). As a result, global health is currently better prepared than it has been historically for

outbreaks from EIDs. However, several shortfalls still remain in practice in the global capacity to respond to such outbreaks.

This paper argues that the characteristics of the diseases, which the international public health community has faced in recent years (H5N1 and H1N1 influenza, SARS, and Ebola and Marburg viruses), have conditioned our international public health response measures significantly. We demonstrate that despite current higher levels of cooperation in global health, the existing pandemic response mechanisms have not yet been tested or conditioned and therefore have the potential to be inadequate to confront an EID outbreak with pandemic potential, which is both highly virulent and highly transmissible.

METHODS

We categorize EIDs by their degree of virulence and transmissibility into four quartiles (Table 1); low virulence and low transmissibility (V_LT_L); low virulence and high transmissibility (V_LT_H); high virulence and low transmissibility (V_HT_L); and high virulence and high transmissibility (V_HT_H). With the exception of V_LT_L events, EIDs in the other three quartiles are potential security threats at national and global levels, with an outbreak from a V_HT_H disease being the most potentially dangerous security threat to global health.

We also identify the most important steps of surveillance and response measures to prevent the spread of outbreaks of EIDs: case reporting, molecular diagnostics, rapid containment and mitigation measures including non-pharmaceutical measures (which included vaccine development and aggregate production capacity, deployment and vaccination, vaccine and antiviral agent stockpile and vaccine benefit sharing). We then assess the existing capacity of global public health to effectively prevent the spread an EID outbreak by evaluating the conditions created by the three different types of EIDs (V_LT_H, V_HT_L and V_HT_H).

We examine recent outbreaks of EIDs to assess the existing readiness of global health institutions to adequately address the steps above, and examine their likely effectiveness against outbreaks from V_LT_H, V_HT_L and V_HT_H diseases. Since there are no recent cases of a V_HT_H outbreak (e.g. the pandemic of Spanish influenza in 1918-1919),[7] we therefore make inferences based on recent outbreaks of V_LT_H and V_HT_L cases.

CASE REPORTING

One of the main challenges for early case detection and reporting is the asymptomatic nature of some EIDs. An influenza-like disease can easily spread under the guise of seasonal influenza and hence could be difficult to detect early. Such lag in detection can exist in a potential V_LT_H case with low CFR. However, the case reporting for the V_HT_L and V_HT_H diseases would be expected to be swifter during the initial period due to their high CFR. In fact, a V_HT_H case is likely to overwhelm health facilities following inception, triggering swift attention from health authorities.

Case reporting has improved due to the advancement in public health measures in many countries. However, there remains geographic disparity in case reporting. Within a month of the first cases of H1N1 outbreak in Mexico in 2009, the Mexican Directorate General of Epidemiology issued a national epidemiological alert and called

for strengthening surveillance measures. A comprehensive study conducted later, however, shows that delay in hospitalization had an impact in the CFR.[8] The delays were due to the nonspecific nature of influenza virus. Drawing conclusions from Mexico's case, the study further suggests that besides antiviral treatment rates, "admission delays could partly explain the reported variability in pandemic mortality burden between high and middle income countries."[9]

Also, a major concern is that a country experiencing an EID outbreak may conceal case reporting and withhold information from WHO and other countries contrary to the binding IHR guidelines.[10] There are a variety of reasons this may occur. One is the inherent uncertainty about the causal agent, particularly new strains or unknown pathogens. Lack of certainty may lead to extra precautions such as travel and trade restrictions, which may affect the economy and trigger widespread panic. During the 1994 potential outbreak of a plague in India, over 500,000 individuals fled, and the cancellation of flights, closure of schools and restriction of food trade caused significant economic cost.[11] India suffered over $30 million in tourist trade alone, with total loss of over a billion.[12] Later the CDC and WHO declared that the precautionary measures imposed by India were unnecessary.[13]

However, the consequences from concealing an emerging EID outbreak can also be detrimental. China's reluctance to share information about the SARS outbreak inhibited other countries from taking early measures in 2002-2003.[14] Nevertheless, countries are increasingly realizing the benefits of sharing information during a disease outbreak, in part because it enables them to gain access to necessary resources under WHO. A change of behavior was evident when China shared information and cooperated with WHO during the H1N1 outbreak in 2009 (albeit on an outbreak caused by a known pathogen) and the H7N9 outbreaks in 2013 (albeit the reporting of initial H7N9 outbreak cases was not beyond controversy).[15] Therefore, based on the aforementioned assessment, any optimism in the effectiveness of current surveillance processes for case reporting against potential V_HT_L and V_HT_H cases should be welcomed with caution.

MOLECULAR DIAGNOSTICS

Molecular diagnostics help identify the characteristics of the pathogen responsible for an outbreak and are the first step in the development of vaccines. However, there are a few shortcomings in early molecular diagnostics. First, there is a global disparity between high-income and low-income countries, in expertise and capacity for comprehensive biosurveillance efforts. For example, within WHO's GISN, despite having 136 National Influenza Centres (NICs) in 106 countries for early detection, "[The] GISN has geographical gaps, especially in Africa."[16] Only one out of twelve WHO reference laboratories for diagnosis of influenza A/H5 infection is located in Africa.[17] Only one WHO Collaborating Center for Influenza and Essential Regulatory Laboratory is located in China, with the other eight located in Japan, Australia, the U.S. and the U.K.[18]

Nevertheless, the global disparity in the capacity for molecular diagnostics could be averted by increasing regional cooperation for resource sharing and capacity building. There is evidence of this activity; under the WHO umbrella, the WHO African Regional Office (AFRO) has developed the Integrated Disease Surveillance and

Response Network (IDSR), involving 43 out of 46 African countries.[19] Additionally, although Mexico did not have advanced laboratory diagnostic capabilities during the 2009 H1N1 influenza outbreak, cooperation led to samples being sent to the Public Health Agency of Canada's (PHACs) National Microbiology Laboratory in Winnipeg and to the CDC in Atlanta.[20] This collaboration was possible due to the trilateral agreement under the Security and Prosperity Partnership of North America initiative launched in 2005. These laboratories confirmed the H1N1 virus cases to WHO.[21]

There are also precedents of cooperation in capacity building to improve epidemiological surveillance in developing countries. There are valuable training programs run in collaboration with the U.S. CDC and developing countries for capacity building under the worldwide Field Epidemiology Training Program (FETP/FELTP).[22] The CDC and PHAC have helped set up real-time PCR machines for molecular diagnostics in Mexico after the 2009 H1N1 outbreak.[23] Canada and the U.S. also helped train molecular biologists in six different states in Mexico,[24] illustrating that regional cooperation can improve biosurveillance in developing countries that lack technological expertise and capacity. According to WHO, many laboratories in developing countries have recently acquired real-time PCR capacity.[25] However, there exists a lack of clear information about the number and rate of such technology transfers and the relevant skill-development assistance for many countries.

Despite the existing plans and initiatives for regional cooperation, the early detection process of an EID might be compromised due to delays during sample sharing for identification, as it happened in the H1N1 case in Mexico. Although the CDC is the WHO Collaboration Centre for Mexico, biological samples were sent from Mexico to Canada and the U.S. on the same day. The virus was first detected at PHAC in Canada, in part since the U.S. authorities held up the samples for 24 hours.[26] Therefore, it took three days to confirm Mexico's H1N1 case, even with regional cooperation. It is crucial to note that since the initially reported case in March 2009, Mexico was already witnessing the outbreak by early April 2009.[27] Delays in sample sharing may be due to legal and bureaucratic hurdles relating to proprietary reasons, desire for credit and recognition, lack of agreements on transfer protocol, uncertainty around authority and authorization, and other unintended and intentional reasons.

Since vaccine development for a new virus depends on the pathogen's successful identification, a three-day lag could be a matter of great concern in a potential V_HT_H case. To elucidate how efficient developing countries might be in sample sharing and testing in case of a potential V_HT_H case, we examined Ebola outbreaks in Africa, since Ebola shares the high CFR characteristics of a V_HT_H case.[28]

Unfortunately, there are ambiguities on the efficacy of biosurveillance in the African region, due to lack of information. Only the 2001 and 2004 Ebola outbreaks report the time taken for sample sharing and identification. During the 2001 Ebola outbreak, the sample was sent within 20 days of the initially reported cases to Gabon's Centre International de Recherches Medicales de Franceville (CIRMF) laboratory.[29] There, the pathogen was identified within a day. During the 2004 Ebola outbreak in Sudan, the sample was collected by the Kenyan laboratory officials from the Kenya Medical Research Institute (KEMRI) lab within three days of the initially reported cases of Ebola.[30] The pathogen was identified within seven days, and confirmed by the CDC five days after. These two cases show that despite limited biosurveillance capacity in Africa, rapid sample collection and identification were carried out by the regional labs

under WHO's guidance. However, a 2010 research study identified delayed reporting and inadequate documentation due to the difficulties in linking laboratories and disease surveillance data in Africa.[31] As a result, there are ambiguities in information concerning biosurveillance capacity despite positive regional cooperation.

RAPID CONTAINMENT

Rapid containment procedures including non-pharmaceutical steps,[32] such as public health information and communication, prophylactic measures, isolation, quarantine, social distancing, travel restrictions, border control, effective treatment of infected patients and vigorous case tracking, are measures for immediate response against an EID outbreak. These measures can occur within countries (local or regional containment) or at their borders (transborder containment). However, there is an ambiguity about the requirements for initiating rapid containment measures. WHO's Interim Protocol for rapid containment specifically mentions that severity should not be a motivating factor for rapid containment.[33] At the same time, it says if the virus has already spread too far, then the containment should not be initiated.

It was already too late to initiate transborder containment during the H1N1 pandemic in 2009, despite relatively early detection.[34] By the end of April, 18 countries confirmed reported cases of H1N1 including the U.K., Israel and New Zealand.[35] This demonstrates that transmission to multiple countries beyond the state of origin might be unavoidable, despite early detection of the pathogen. Therefore, the window of opportunity to initiate rapid containment is very short.[36] Several countries undertook containment measures during the H1N1 outbreak. For example, China took strong risk-averse measures such as airport screening of incoming passengers, quarantining suspected patients, contact tracing, on-board airplane temperature checks and suspension of flights from Mexico at the earlier stage of the H1N1 outbreak.[37] Despite such containment measures, China could not avoid the H1N1 outbreak entering its population. However, this is not to say that rapid containment is impossible when transmission is modest and clinical reporting of cases is timely.

In case of transborder H1N1 transmission, findings by Baker et al. suggested that the risk of on-flight transmission could be 'low'.[38] Kahn et al. found a 'remarkably strong degree of correlation' in the H1N1 transmission between Mexico, the origin of the travelers and the destinations.[39] On the ground, the effectiveness of airport screening measures is also questionable[40] as Canada raises doubt from its experience with SARS outbreak.[41] Therefore, the potential effectiveness of transborder containment remains ambiguous.

In contrast to the examples above, Ebola outbreaks in Africa are among the few EID outbreaks that were rapidly contained. Containment procedures included close surveillance with active case-finding, daily follow-up of contacts during the incubation period, isolation of the patients, safe burial practices and social mobilization.[42] During the 2001 outbreak in Gabon, a large group of dedicated health workers, volunteers, international observers and the Ministry of Defence of Gabon were involved. Gabon's experience was implemented in subsequent Ebola outbreaks in Sudan, the Democratic Republic of Congo, Uganda and the Republic of Congo.[43] As a consequence, despite the high CFR, the Ebola outbreaks in Africa were adequately contained.

Rapid containment worked in the Ebola outbreaks because the pathogen, despite being highly infectious and lethal, requires close contact for human-to-human transmission; thus isolation procedure easily contained transmission.[44] Moreover, the incubation period of Ebola virus was a maximum of 21 days, which provided ample time to track and monitor affected individuals for isolation, and Ebola has a low rate of subclinical illness, meaning most infected individuals were able to be identified. As a result, Ebola and similar viruses like the Marburg virus were appropriately contained. Similarly, the SARS virus has an incubation period of maximum 10 days, which provided enough time to trace the origin of transmission and the suspected patients that helped to contain it fast.[45] Furthermore, transmission was possible only in close proximity, which is why most of the transmission occurred in hospitals. The outbreak was controlled when hospital transmission was controlled through infection-control practices and isolation procedures.[46] Therefore, it is likely that a disease outbreak of a V_HT_L can be successfully contained provided the incubation period allows ample time to trace contacts and adequate and timely public health responses are taken.

However, it is difficult to contain a V_LT_H disease such as the H1N1 virus, which has a very small incubation period of 1-3 days.[47] Short incubation period and low generation time for 'Influenza-like Illness' (ILI) makes such disease difficult to contain.[48] Also, initial symptoms of influenza flu can easily be overlooked since it is difficult to differentiate an 'Influenza-like Illness' (ILI) caused by a lethal new virus from that caused by a familiar B or C type influenza virus.[49] Moreover, if the outbreak takes place during influenza season, early detection becomes much more difficult since the initial outbreak could be mistaken for seasonal influenza. Therefore, the possibility is high that by the time an outbreak of an influenza virus like 2009 H1N1 is detected, it is already transmitted to multiple communities, if not multiple countries.

This condition is aggravated by the lack of clear information due to rapid transmission, as discussed above, which makes decisions to initiate rapid containment more difficult. During the H1N1 outbreak, WHO's Emergency Committee debated whether or not to initiate rapid containment measures in their second meeting on April 27, 2009.[50] The evidence of virulence available to the Emergency Committee was still incomplete at that time. As a result, Dr. Fukuda, the Assistant Director-General of WHO, said in a press release, "Given the current situation, the current focus of efforts should really be on mitigation efforts rather than trying to contain the spread of the virus, predominantly because this virus has already spread quite far, and at this time, containment is not feasible operation."[51] It was further advised that border closures and travel restrictions would be ineffective. WHO's revelation that rapid containment was not possible came within less than one month of the H1N1 outbreak in Mexico. The unfeasibility of rapid containment was due to the rapid transmission.

In case of a V_HT_H outbreak, it is likely that a higher fatality rate would cause the outbreak to be noticeable earlier. The 1918-1919 Spanish influenza pandemic had fatality rate of 2-3%,[52] whereas the H5N1 virus had a fatality rate of 60%. If the H5N1 virus evolves to be efficient in human-to-human transmission and emerges as a potential V_HT_H outbreak, which is considered plausible,[53] it is reasonable to expect the fatality count to be much higher during the initial period of the outbreak.[54] As a result, the emergency responses from governments in affected nations and WHO may be faster. However, that may not help gain a window of opportunity sufficient to initiate successful rapid containment measures. A short incubation period, novelty and lethality

of the pathogen could make rapid containment measures difficult. One of the mathematical models of rapid containment shows that its success is possible only under "several logistically formidable conditions," such as, "rapid case detection and treatment of targeted group (preferably in <48h), effective delivery of treatment to a high proportion of the population (>90%), sufficient drug stockpiles (>3 million courses) and population cooperation."[55] Wearing, Rohani and Keeling have also argued that the assumption that these conditions will be met is 'unrealistic' and 'overoptimistic.'[56] Also, it is likely to be impossible to contain a novel pathogen that is highly virulent and transmissible simply because of lack of functional knowledge about its clinical characteristics and other essential aspects. However, the success of transborder containment will ultimately depend on various characteristics of the responsible pathogen, degree of cooperation of the affected and at-risk populations, and availability of necessary resources. In light of the arguments above, our understanding of the ability for rapid containment measures to a potential V_HT_H case in future are currently uncertain.

MITIGATION

Mitigation measures are implemented when rapid containment is unfeasible and the pandemic is suspected to prevail for a longer period. During the 2009 H1N1 influenza pandemic, Mexico implemented community mitigation measures including social distancing, closure of schools, restaurants, theatres and archeological sites, and restriction on public gatherings such as sports and religious events.[57] WHO advocated for mitigation processes globally and discouraged unnecessary traveling instead of a categorical restriction.

However, mitigation can be difficult because pandemics may resurge even after an initial drop in cases, which was evident during the 2009 H1N1 pandemic. Concurrent seasonal influenza in the Northern Hemisphere, cooler dry weather and resumption of school contributed to the resurgence of the H1N1 cases in Northern Hemisphere countries.[58] Therefore, should a V_HT_H case be influenza, such as H5N1, it will unavoidably coincide with seasonal influenza, either at the beginning (potentially inhibiting detection) or at the end (potentially causing a resurgence).[59] Nevertheless, mitigation procedures can be effective, with the caveat that success will likely depend, at least in part, on one of the most essential measures, vaccination. Vaccination depends on a number of steps, including vaccine development and aggregate production capacity, deployment, vaccine and anti-viral stockpile, and vaccine benefit sharing, discussed in detail below.

Vaccine Development & Aggregate Production Capacity

Currently, more than 250 million doses of influenza vaccine are produced annually.[60] However, current production capacity is inadequate for a pandemic and is also incapable of rapid expansion. Survey reports conducted in 2009 estimate vaccine production capacity by pharmaceutical companies at a maximum 4.9 billion doses in 12 months,[61] to a conservative estimate of 1 and 2 billion doses in 12 months.[62] The maximum capacity is estimated to be achievable only if total global capacity is dedicated to the production of one vaccine with optimal saving procedure of antigen.[63] This means

that, in case of a potential pandemic, at a time when the disease most likely will have spread in more than one region of the world, there will be shortfall for vaccine production either for the new disease or for diseases for which other vaccines are being produced (e.g. seasonal influenza).[64] During the 2009 H1N1 pandemic, the CDC hoped that 40 million doses would be available by the end of October. However, the CDC Director also expressed his skepticism that delay in manufacturing process may result in a shortfall of 10-12 million doses.[65] In fact, unexpected production problems further delayed the vaccine supply. By April 2010, the U.S. alone bought 229 million doses of H1N1 vaccines, out of which only 81-91 million doses were administered leaving 138 million doses unused because the demand dissipated by the time they were available.[66] There could be other complications as well, such as the effectiveness of a vaccine. Hundreds of thousands of vaccines were recalled during the H1N1 pandemic vaccination process because they were not as potent as they should have been. The French manufacturer Sanofi Pasteur alone recalled 800,000 doses of vaccines.[67]

Besides this shortfall problem, an average of at least 6-9 months is needed to characterize the responsible pathogen to develop vaccines; meaning early detection and identification of the responsible pathogen is crucial for vaccine development and timely vaccination.[68] Relatively early vaccine development in the H1N1 was facilitated by the fact that it was a known strain. In case of an outbreak from an unknown strain, the delay in vaccine development could be substantial. Such delay suggests a lag of about one year with no effective remedy for a deadly $V_H T_H$ case from an unknown strain. Furthermore, the CFR will be exacerbated if the initial outbreak takes place in a densely populated region. As a result, the capacity to develop and produce a sufficient amount of vaccine is still inadequate in case of a $V_H T_H$ disease for a world population of over 6 billion. Therefore, capacity development for vaccine production is a major issue that needs consistent global attention.

Vaccine Deployment

Anti-microbial agents are sometimes effective to minimize the spread of EIDs in absence of an effective vaccine. WHO has managed to store $5 million doses of anti-viral agents donated by the manufacturer Roche in addition to the developed countries' contribution to WHO's virtual stockpile. The stockpiles are stored in two different locations and a systematic chain of deployment was developed, which was tested during the 2009 H1N1 pandemic.[69] WHO also demonstrated swift actions in ensuring donor countries' cooperation for vaccine deployment during the H1N1 pandemic in 2009. Within 9 months of the H1N1 pandemic, from March to November, WHO managed pledges of 200 million doses of vaccines, out of which 122.45 million doses were actually committed by the donor countries.[70] This amount was sufficient to meet at least 10% population coverage of the eligible countries with outbreaks.

Nevertheless, there are reasons for a concern in vaccine deployment for a future $V_H T_H$ case. First, there are reported cases of delay in vaccine deployment during the 2009 influenza pandemic. Although the vaccine production started in September and the U.S. started immunization in early October, Mexico waited until mid-January for immunization against the H1N1.[71] Inadequate quantity and accessibility issues were responsible for this delay. Despite the aforementioned world production capacity of vaccines in 2009, inadvertent consequences from delays in vaccine deployment might

be unavoidable in case of another pandemic in future; additionally, changes in population acceptance of and willingness to get vaccinated could have dramatic impacts on successful deployment. The consequence may be thousands of deaths in a V_HT_H case.[72]

Vaccine & Anti-viral Agents Stockpile

There is a stark contrast between high-income and low-income countries concerning the stockpile of vaccine. On one-hand, high-income countries have high targets for vaccine stockpile. For example, the U.S. has a target of vaccine stockpile at 25% of its population as noted by its Pandemic Response Plan,[73] although various organizations such as the Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiology of America advocate an ideal target of stockpile at 40% of its population.[74] On the other hand, most of the developing countries cannot even afford to maintain a stockpile of vaccine, given the high costs associated with purchasing and maintaining such stockpiles.

For a viral EID, anti-viral agents such as M2 Ion-channel inhibitors and Neuraminidase inhibitors could be effective to minimize the spread of the virus in absence of a vaccine. However, there is a significant difference in the costs associated to maintain stockpile of anti-viral agents between high-income and low-income countries.[75] WHO planned to include 150 million doses of H5N1 vaccine in its stockpile with the goal of dispensing 50 million doses for use in an affected country in the future. The rest of the 100 million doses will be reserved for developing countries' use if the pandemic emerges.[76] However, adequate information is not available concerning the progress of WHO's stockpile program.

Vaccine Benefit Sharing

Cooperation between high-income and low-income countries is also essential for effective vaccine development programs. During the H1N1 pandemic in 2009, several countries with vaccine production capacity were licensed by September 2009, which include Australia, China, the U.S., Japan and several other countries in Europe.[77] However, many middle-income and low-income countries did not have the financial resources to ensure initial supplies. In response, the U.S., Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland and the U.K. announced donations of vaccines to the developing countries under WHO's coordination.

Also, fairness in vaccine accessibility has been a major concern among developing countries. It became an international issue when Indonesia stopped sharing pathogen samples with WHO's GISN system in 2005.[78] After four years of negotiation, the landmark agreement signed by WHO member states in April 2011, made significant progress in addressing virus sample and benefit sharing issues.[79] According to the terms of the Standard Material Transfer Agreements (SMTA), it is mandatory for the pharmaceutical companies to form financial partnership with WHO to cover 50 percent of the annual running costs of vaccination, provide various options for vaccine donation, and grant vaccine development license to the developing countries in case of a pandemic.[80] This created possibilities to produce vaccines cheaply by pharmaceutical companies in developing countries.[81] As a result, WHO has made significant progress in

vaccine benefit sharing, albeit it does not effectively offset the shortcomings in other issues related to vaccines as demonstrated by three previous factors.[82]

DISCUSSION AND CONCLUSION

As global governance has increasingly become a norm of institutional practice in resolving 'problems without borders',[83] global health has drawn significant attention from states and non-state actors. Diplomacy, what once belonged to the practice of foreign affairs, has also received a new dimension in practice with its nomenclature of 'health diplomacy' in response to the practical demand for cross-border cooperation, coordination and negotiation on global health issues. The traditional dichotomy of public vs. private, state vs. non-state, and global vs. local has dissolved through the institutional practice in global health. By framing health as a 'security' issue,[84] development in understanding and policy-making on global health has taken a sharp turn,[85] which saw the increasing importance of medical and public health experts in health security.[86] The global level crisis assessment program under WHO, cooperation on vaccines by the Developing Countries Vaccine Manufacturers Network, International Vaccine Institute, Global Health Investment Fund and BARDA, and renewed attentions by the G8/G20/BRICS members, demonstrate significant progress in institutional practice of global health.[87] As these developments are very positive, it is also increasingly challenging to maintain the momentum, due to institutional fatigue often caused by fiscal austerity, misperception of threat level, sovereignty problem and organizational pathology. This is a concern also in global capacity building for preventable measures and crisis management of pandemic response from EIDs. Improvements in pandemic governance may slow and resources committed to EID governance may dwindle. Recent cases of the MeKong Basin Disease Surveillance (MBDS) losing external funding in 2011,[88] suspension of funding by the Pentagon for vaccine development against Ebola,[89] and the findings of the National Biosurveillance Advisory Subcommittee (NBAS) of the CDC demonstrate some of the growing trends of loss of interest concerning global governance of EIDs despite significant progress in other areas.[90]

Furthermore, existing civil-military cooperation in information sharing and capacity building among different states needs to be sustained. In case of large outbreaks from EIDs, a dedicated large team is necessary, not only for reestablishing security but also for tracking cases, deploying anti-virals and vaccines, and managing compliance for public health measures, such as isolation and quarantine of large groups.[91] Using existing military force's strong chain of command and its rapid deployment capability is one way of successfully meeting this need.[92] We acknowledge the existing civil-military programs in capacity building.[93] However, as Kamradt-Scott contends (arguably) that states with their dynamics of sovereignty ultimately become the most important actor during a major crisis,[94] we suggest that diverting resources to non-combat military resources can provide opportunities for confidence building between countries with critical strategic relations, such as US-China, China-India, and China-Taiwan, by undertaking joint simulation exercises for community-centered and mega city-centered EID outbreaks with high CFR and transmission rate.[95]

Finally, WHO needs closer cooperation with pharmaceutical companies that will produce the first batches of vaccines during a severe pandemic. Despite the progress

made as a result of the 2011 SMTA, the need for closer observation and cooperation between WHO and pharmaceutical companies will remain a significant issue during a V$_H$T$_H$ pandemic. WHO needs to establish a cooperative observation and deployment body so that during a V$_H$T$_H$ pandemic pharmaceutical companies do not compromise WHO's responsibility to deploy vaccines to the affected middle- and low-income countries. This is a significant factor since the affected high-income countries, with their financial resources and geographical location of pharmaceutical companies, can influence the supply of vaccines in their favor. Also, countries may claim their sovereign rights as an excuse for access to limited resources to mitigate the effect of pandemic in their own constituencies.[96] Therefore, WHO's involvement needs to be strong and pressing to ensure that the affected countries have timely access to the initial batches of vaccines. Indeed, WHO has the authority to resolve any 'us and them' suspicion among the developing South as the notion still prevails that health has been increasingly securitized by the leading countries of the West for their own benefit.[97]

The lessons learned during the 2009 H1N1 pandemic, rapid containment success in African Ebola outbreaks, and low mortality in SARS and H5N1, demonstrate progress in the global pandemic response mechanism. Nevertheless, several shortfalls remain requiring attention and resources. A pandemic from an EID, which is both severe and efficient in human-to-human transmission will require strong global leadership and cooperation by regional and national actors. Although several state and non-state actors have diverted their attention and resources to this security threat in the past few years, relative success in recent outbreaks may create complacency.[98] Furthermore, securitization against pandemic threat is a process that depends not only on commitments by the responsible actors but also on continuous institutional evaluation, adaptation and innovation. It is highly likely that when the threat is not imminent, visible and easily measurable, securitization processes may receive lax attention as Kamradt-Scott and McInnes show material factors are also necessary besides 'speech act' for effective securitization through policy measures. However, continuous improvement is needed in almost all the response steps and counter-measures for effective pandemic readiness against a highly virulent and transmissable EID. Therefore, a lag in an EID outbreak may weaken the current global health institutions against a future severe pandemic from an EID.[99] As result, academic, scientists and non-governmental communities need to be vigilant that the commitment by the national and global actors does not diminish in the future.

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Acknowledgements

Table 1: Categorization of EIDs by the degree of their virulence and transmissibility

		Transmissibility	
	Intensity	Low	High
Virulence	Low	(1st Quartile: V_LT_L) C type Influenza	(2nd Quartile: V_LT_H) 2009-2010 H1N1
	High	(3rd Quartile: V_HT_L) H5N1, SARS, VHF (Ebola, Marburg)	(4th Quartile: V_HT_H) 1918-1919 H1N1

[1] The CFR was over 80% in Democratic Republic of Congo (1998-2000) and even higher in Angola outbreak in late 2004. "Marburg haemorrhagic fever," Global Alert and Response (GAR), WHO. accessed on 23 July, 2012. <http://www.who.int/csr/disease/marburg/en/>

[2] The Spanish Flu had a CFR more than 2.5%. Jeffrey Taubengerge and David Morens, "1918 Influenza: the Mother of All Pandemics," Emerging Infectious Diseases. 12.1 (January 2006): 15.

[3] See section 'Case Reporting' below for more details on economic cost and security implication of an EID outbreak.

[4] Hampson writes about several possible cases of reassortment. Alan W. Hampson, "A Pandemic Waiting in the Wings?," Emergency Medicine Australasia. 18 (2006): 420-429.

[5] Ebola outbreaks in recent years occurred in Congo (2001-2002, 2003, 2005), Sudan (2004), DRC (2007, 2008), Gabon (2001-2002) and Uganda (2000, 2007, 2011). Media Centre, WHO. "Ebola hemorrhagic fever," accessed on 23 July, 2012. <http://www.who.int/mediacentre/factsheets/fs103/en/index.html> Marburg virus outbreaks in recent years occurred in DRC (1998-2000), Angola (2004-2005) and Uganda (2007). "Marburg haemorrhagic fever," Media Centre, WHO. accessed on 23 July, 2012. <http://www.who.int/mediacentre/factsheets/fs_marburg/en/index.html>

[6] For more details, see WHO, Implementation of the International Health Regulations (2005). (2011).

[7] Jeffrey Taubengerge and David Morens, "1918 Influenza: the Mother of All Pandemics," Emerging Infectious Diseases. 12.1 (January 2006): 15-22.

[8] WHO, Implementation of the International Health Regulations (2005). (2011), 51; Gerardo Chowell et al., "Impact of Antiviral Treatment and Hospital Admission Delay on Risk of Death Associated with 2009 A/H1N1 Pandemic Influenza in Mexixo," *BMC Infectious Diseases*. 12.97 (2012): 1-11.

[9] Ibid. 9.

[10] A country can withhold information-sharing fearing travel and trade restriction by other countries, hampering its economy considerably. During the SARS outbreak, WHO imposed temporary travel restriction to Beijing and Toronto against both countries' extreme dissatisfaction. Jiyong Jin and Joe

Karackattu, "Infectious Diseases and Securitization: WHO's Dilemma," Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. 9.2 (2011), 183.

[11] Jennifer B. Nuzzo and Gigi Kwik Gronvall, "Global Health Security: Closing the Gaps in Responding to Infectious Disease Emergencies," Global Health Governance. 4.2 (Spring 2011): 6.

[12] Ibid.

[13] Ibid.

[14] Rachel D. Schwartz and Jonathan Schwartz, "Confronting Global Pandemics: Lessons from China and the U.S.," Global Health Governance . 3.2 (Spring 2010),13-15.

[15] Keith Bradsher, "China's Actions in Flu Cases Draw Critics," *The New York Times*. April 10, 2013. accessed March 12, 2014. < http://www.nytimes.com/2013/04/11/world/asia/delay-on-china-avian-flu-announcement-questioned.html?pagewanted=all&_r=0>, Wang Hongyi and Wu Ni, "Authorities Deny Delay in H7N9 Reports," *China Daily*. April 11, 2013. accessed March 12, 2014. < http://europe.chinadaily.com.cn/china/2013-04/11/content_16391666.htm>

[16] WHO, Implementation of the International Health Regulations (2005). (2011), 42.

[17] WHO, WHO Reference Laboratories for Diagnosis of Influenza A/H5 Infection. March 28, 2011. accessed February 28, 2012. <http://www.who.int/influenza/gisrs_laboratory/h5_reflabs/list/en/index.html>

[18] WHO, WHO Collaborating Centres for Influenza and Essential Regulatory Laboratories. accessed February 28, 2012. <http://www.who.int/influenza/gisrs_laboratory/collaborating_centres/list/en/index.html>

[19] Even though WHO and CDC have made significant progress for regional and global cooperation for surveillance, some of the regional plans for pandemic response have rarely mentioned explicit cooperation with neighboring countries. Pandemic response plans of European Union(2005), Latin America (2007) and Africa (2007) are some of them. However, there has not been any update available on these plans. Mujica et al. also claims that regional and inter-country cooperation still remains a key challenge. For a detailed review, see Sandra Mounier-Jac and Richard J Coker, "How prepared is Europe for pandemic influenza? Analysis of national plans," The Lancet. 367 (April 2006): 1405-1411. Giuseppina Ortu, Sandra Mounier-Jack and Richard Coker, "Pandemic Influenza preparedness in Africa is a profound challenge for an already distressed region: analysis of national preparedness plans," Health Policy and Planning. 23 (2008): 161-169, Ana Mensua, Sandra Mounier-Jack and Richard Coker, "Pandemic influenza preparedness in Latin America: analysis of national strategic plans," Health Policy and Planning. 24 (2009): 253-260 and O. J. Mujica, O. Oliva, T. dos Santos, and J.P. Ethrenberg, "Preparedness Planning for an Influenza Pandemic: Regional Efforts," Pan American Journal of Public Health. 23.6 (June 2008): 428-34.

[20] Ying Zhang, Hugo Lopez-Gatell, Celia M. Alpuche-Aranda, and Michael A. Stoto, "Did Advances in Global Surveillance and Notification Systems Make a Difference in the 2009 H1N1 Pandemic?– A Retrospective Analysis," PLoS One, 8.4 (2013). Accessed March 13, 2014. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3616047/pdf/pone.0059893.pdf >

[21] 16 of the 17 samples were found positive and same strain was isolated by the CDC from California.

[22] For more details, see the CDC website on FETP, < http://www.cdc.gov/globalhealth/fetp/> accessed March 12, 2014.

[23] Real time PCR machines are advanced tools for molecular diagnostics of diseases.

[24] Jon Cohen, "Exclusive: Interview with head of Mexico's Top Swine Flu Lab," Science Insider. May 1, 2009. accessed May 12, 2012. <http://news.sciencemag.org/scienceinsider/2009/05/exclusive-inter.html>

[25] WHO, "Detection of Influenza Virus Subtype A by Polymerase Chain Reaction: WHO External Quality Assessment Project Summary Analysis, 2011," Weekly Epidemiological Record. 3 (2012): 29, and WHO, "Establishment of PCR laboratory in developing countries," (2011):2, accessed March 15, 2012. <http://www.searo.who.int/LinkFiles/Publications_SEA-HLM-419.pdf>

[26] Celia Alpuche, the head of Mexico's Instituto de Diagnóstico y Referencia Epidemiológicos (InDRE) could not provide an explanation for the 24 hours delay at the CDC. Jon Cohen, "Exclusive: Interview with head of Mexico's Top Swine Flu Lab," Science Insider. May 1, 2009. accessed February 28, 2012. <http://news.sciencemag.org/scienceinsider/2009/05/exclusive-inter.html>

[27] There was a community of 2,600 with 444 reported cases in Mexico by March.

[28] A recent study on the trends of major disease outbreaks in Africa demonstrates that viral hemorrhagic fevers (VHFs) such as Ebola (CFR 53%) and Marburg (CFR 89%), and other EIDs such as human monkey pox (CFR 1.5%) are growing endemics in African countries. Senait Kebede et al. "Trends of major disease

outbreaks in the African region, 2003-2007," East African Journal of Public Health. 7.1 (March 2010): 20-21.

[29] The initial Ebola cases were reported on 17 November 2001. WHO, "Outbreak(s) of Ebola Haemorrhagic Fever, Congo and Gabon, October 2001-July2002," Weekly Epidemiological Record, WHO. 78 (2003): 225-226.

[30] For more details of the outbreak, see WHO, "Outbreak of Ebola Haemorrhagic Fever in Yambio, South Sudan, April-June 2004," Weekly Epidemiological Record, WHO. 43 (2005): 370-371.

[31] WHO initiated the Integrated Disease Surveillance and Response (IDSR) in Africa to improve the biosurveillance capacity in a number of African countries. This research study assesses the effectiveness of the system. For details, see P. Nsubuga et al., "Implementing Integrated Disease Surveillance and Response: Four African Countries' Experience, 1998-2005," Global Public Health. 5.4 (July 2010): 364-380.

[32] WHO, "WHO Global Influenza Preparedness Plan," (2005). accessed March 15, 2014. http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_5.pdf ; also see WHO Writing Group, "Nonpharmaceutical Interventions for Pandemic Influenza, International Measures," Policy Review, 12.1 (January 2006). Accessed March 15, 2014. < http://wwwnc.cdc.gov/eid/article/12/1/pdfs/05-1370.pdf >

[33] The virological and epidemiological requirements for such decision does not depend on the CFR. According to the protocol, the reason is that any mild start can end up into a severe case. WHO, WHO Interim Protocol: Rapid Operations to Contain the Initial Emergence of Pandemic Influenza. (October 2007), 8, 10.

[34] "Although it was detected too late for rapid containment, there was immediate virus sharing so a rapid risk assessment was possible along with immediate commencement of development of diagnostic tests and vaccines." A. Nicole et al. "Experience and lessons from surveillance and studies of the 2009 pandemic in Europe," Public Health. 124 (2010): 22.

[35] Such rapid transmission took place despite having a prompt response from WHO. During the 2009 Pandemic Flu, WHO already activated SHOC, facilitated by the SPG by 25 April. WHO's regional offices were also active in information sharing by communicating between the WHO headquarter and the national and local actors under GOARN as soon as the outbreak was identified in Mexico in mid-March.

[36] See the 'Case Reporting' section.

[37] Rachel D. Schwartz and Jonathan Schwartz, "Confronting Global Pandemics: Lessons from China and the U.S.," Global Health Governance. 3.2 (Spring 2010):16.

[38] The study suggests that the measurable risk of transmission of pandemic influenza during commercial air travel is low and follow up of passengers with symptoms could be difficult despite vigorous public health measures. Michael G. Baker et al., "Transmission of Pandemic A/H1N1 2009 Influenza on Passenger Aircraft: Retrospective Cohort Study," British Medical Journal. 340.c2424 (2010): 6.

[39] However, this study used 2008 flight itineraries for 2009 pandemic transmission. Kamran Khan et al., "Spread of a Novel Influenza A (H1N1) Virus via Global Transportation," The New England Journal of Medicine. 361.2 (July 2009): 213.

[40] The U.S. scientists reported, "The basic premise of the proposed revision, that the identification and quarantine of airline passengers showing symptoms of influenza infection will significantly diminish the spread of pandemic fly, is highly questionable and unsupported by data….The assumption that we can stop a pandemic illness of SARS or influenza by monitoring air travel is not correct." David M. Drummond and Christina M. Drummond, "Avian Influenza Pandemic Threat and Health Systems Response," Emergency Medicine Australasia. 18(2006):439.

[41] A total of $7.55 million was spent from 18 March to 5 July, 2006 for screening measures in Canadian airports, which found no results of SARS. The study suggests that this money would have produced better results if used at the hospital entry points. Ronald K. St. John, "Border Screening for SARS," Emerging Infectious Diseases. 11.1 (January 2005): 9.

[42] WHO, "Outbreak(s) of Ebola Haemorrhagic Fever, Congo and Gabon, October 2001-July 2002," Weekly Epidemiological Record. 26.27 (2003): 223.

[43] WHO, "Outbreak of Ebola Haemorrhagic Fever in Yambio, South Sudan, April-June2004," Weekly Epidemiological Record. 43.80 (2005): 371.

[44] R_0 of Ebola virus ranges from 1.34 to 1.84, G. Chowell et al., "The basic reproductive number of Ebola and the effects of public health measures: the cases of Congo and Uganda," The Journal of Theoretical Biology. 229.1 (2007): 119-120.

[45] The incubation period of SARS was even longer in Hong Kong's cases.

[46] Eric S. Toner and Jennifer B. Nuzzo, "Acting on the lessons of SARS: what remains to be done?," Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. 9.2 (2011):170.

[47] David A. Bradt and Christina M. Drummond, "Avian influenza pandemic threat and health systems response," Emergency Medicine Australasia. 18 (2006): 432.

[48] The generation time is "the doubling time, or the time required for the number of infections to double in size." ILI has a generation time of 2.4-3.1 days. "2009 H1N1 Early Outreabk and Disease Characteristics," Centers for Disease Control and Prevention. October 27, 2009. accessed August, 12, 2012 <http://www.cdc.gov/h1n1flu/surveillanceqa.htm>

[49] Influenza viruses are three types: A, B and C. Influenza type C causes mild respiratory illness. B and A types are concern of public health. Influenza B does not have subtypes and mostly affect human population. Influenza A type have two types of protein sugar: haemagglutinin (H) and neuraminidase (N). There are 16 known subtypes of H and 9 known subtypes of N. These combinations together lead to various types of Influenza A viruses, such as H1N1, H2N2, H3N2, H5N1. These are highly infectious zoonotic viruses and are capable of transmitting from other types of animals to human being. See, Alan W. Hampson, "Influenza Virus Antigens and 'Antigenic Drift'," in Influenza. ed. C.W. Potter. (New York: Elsevier, 2002), 49-71.

[50] WHO, Implementation of the International Health Regulations (2005). (2011), 54.

[51] WHO, Transcript of Virtual Press conference with Dr. Keiji Fukuda, Assistant Director-General ad. Interim for Health Security and Environment. April 27, 2009. accessed March 2, 2012. <http://www.who.int/mediacentre/swineflu_presstranscript_2009_04_27.pdf>

[52] However, communication barrier was a major concern in the early 20th century. As a result, geographically isolated area had high mortality from H1N1 in 1918, Svenn-Erik Mamelund, "Geography May Explain Adult Mortality From the 1918-20 Influenza Pandemic," Epidemics, 3.1 (march 2011), 46-60.

[53] H5N1 has relatively longer incubation period compared to other influenza diseases. 2-8 days with a maximum of 17 days among human. "Avian Influenza," Media Centre, WHO. April, 2011. accessed August 1, 2012. <http://www.who.int/mediacentre/factsheets/avian_influenza/en/> However, a recent influential study demonstrated that the H5N1 virus can evolve to be efficient for human-to-human transmission. "Experimental Adaptation of an Influenza H5 HA Confers Respiratory Droplet Transmission to a Reassortant H5 HA/H1N1 virus in Ferrets," Nature. 486.7403 (May 2012). accessed July 30, 2012. <http://www.nature.com/nature/journal/v486/n7403/full/nature10831.html>

[54] Yang Huai et al. "Incubation Period for Human Cases of Avian Influenza A," Emerging Infectious Diseases. 14.11 (November 2008).

[55] David A Bradt and Christina M Drummond, "Avian Influenza Pandemic Threat and Health Systems Response," Emergency Medicine Australasia. 18 (2006): 435.

[56] Helen J. Wearing, Pehman Rohani and Matt J. Keeling, "Appropriate models for the management of infectious diseases," PloS Medicine. 2.7 (e174): 0621-0627.

[57] "Mexico Imposes Swine Flu Measures," BBC News. April 29, 2009. accessed March 15, 2012. <http://news.bbc.co.uk/2/hi/americas/8023820.stm> and Carlos Del Rio and Mauricio Hernandez-Avila, "Lessons From Previous Influenza Pandemics and From the Mexican Response to the Current Influenza Pandemic," Archives of Medical Research. 40 (2009): 678-679. (677-680)

[58] This resurgence was anticipated in Predisent's Council of Advisors on Science and Technology, Report to the President on U.S. Preparations for 2009-H1N1 Influenza. (August 2009), 16. Another research study also suggested of a peak during October and November in Northern Hemisphere, even after a comprehensive vaccination program is undertaken earlier. Duygu Balcan et al., "Seasonal Transmission Potential and Activity Peaks of the New Influenza A(H1N1): A Monte Carlo Likelihood Analysis Based on Human Mobility," BioMed Central Medicine. 7.45 (September 2009): 1-12.

[59] Even after the second peak in February, 2010, WHO was not sure whether the pandemic was in post-peak period. "WHO: A/H1N1 Pandemic Flu Yet to Pass Peak," Xinhua News Agency. February 24, 2010. accessed February 28, 2012. <http://news.xinhuanet.com/english2010/world/2010-02/24/c_13186484.htm>

[60] Zacher, Mark W. and Tania J. Keefe, The Politics of Global Health Governance. (New York: Palgrave Macmillan, 2008), 48.

[61] Jose Luis Valdespine-Gomez et al., "Vaccines against influenza A (H1N1) Pandemic," Archives of Medical Research. 40 (2009): 695.

[62] ibid.

[63] The report shows that the overall production capacity may fall to 40% if these optimal measures fail. Also, Nicolas Collin and Xavier de Radiguès, "Vaccine Production Capacity for Seasonal and Pandemic (H1N1)2009," Vaccine . (2009):5186.

[64] Furthermore, although the production of anti-viral agent also quadrupled in recent years, it will still take a decade to produce anti-viral agents such as Oseltamivir to treat 20% of the world's population. K. Lee and D. Fidler, "Avian and Pandemic Influenza: Progress and Problems with Global Health Governance," Global Public Health. 2.3 (July 2007): 224.

[65] Faico, Miriam. "CDC: Production of H1N1 Flu Vaccine Lagging," CNN. October 16, 2009. accessed on August 1, 2012. <http://articles.cnn.com/2009-10-16/health/h1n1.vaccine.delay_1_flu-vaccine-h1n1-schuchat?_s=PM:HEALTH>

[66] Stein, Rob. "Millions of H1N1 Vaccine Doses May Have to be Discarded." The Washington Post. April 1, 2010. accessed August 12, 2012. <http://www.washingtonpost.com/wp-dyn/content/article/2010/03/31/AR2010033104201.html?hpid=topnews>

[67] Faico, Miriam. "800,000 H1N2 Vaccine Doses for Young Children Recalled; Safety not a Concern," CNN. December 15, 2009. accessed August 12, 2012. <http://articles.cnn.com/2009-12-15/health/flu.vaccine.recall_1_sanofi-pasteur-vaccine-doses-len-lavenda?_s=PM:HEALTH>

[68] Colonel Frank William Sherod II, "Avian Influenza Pandemic May Expand the Military Role in Disaster Relief," U.S. Army War College. (2006): 4.

[69] For a detailed description, see WHO, Implementation of the International Health Regulations (2005). (2011), 107-108.

[70] WHO, Final Pandemic (H1N1) 2009 Vaccine Deployment Update. November 10, 2010. accessed February 15, 2012. <http://www.who.int/csr/disease/swineflu/action/h1n1_vaccine_deployment_final_update_2010_11_10.pdf>

[71] Carlos Del Rio and Mauricio Hernandez-Avila, "Lessons from previous influenza pandemics and from the Mexican response to the current influenza pandemic," Archives of Medical Research. 40 (2009): 679. (677-680)

[72] Dr. Harold Varmus, one of the writers of an influential report from U.S. Health and Human Services Department told in a news conference, "Accelerated delivery of vaccines by even a few weeks can mean saving of thousands of lives." Maggie Fox, "Update 2-New US Pandemic Plan Aims to Speed Products," Reuters. August 19, 2010, accessed January 31, 2012, <http://www.reuters.com/article/2010/08/19/flu-usa-idUSN1923187420100819>

[73] U.S. Department of Health and Human Services, *HHS Pandemic Influenza Plan*. November 2005: 6. accessed May 8, 2014. < http://www.flu.gov/planning-preparedness/federal/hhspandemicinfluenzaplan.pdf>

[74] Colonel Frank William Sherod II, "Avian Influenza Pandemic May Expand the Military Role in Disaster Relief," U.S. Army War College. (2006): 17.

[75] This disparity in stockpile cannot be offset by WHO's stockpile, which is limited in number. Hitoshi Oshitani, Taro Kamigaki and Akira Suzuki, "Major Issues and Challenges of Influenza Pandemic Preparedness in Developing Countries," Emerging Infectious Diseases. 14.6 (June 2008): 876.

[76] Article 6.9.2 of WHO, Pandemic influenza Preparedness Framework, 2011. (2011),19.

[77] Jose Luis Valdespine-Gomez et al., "Vaccines against influenza A (H1N1) Pandemic," Archives of Medical Research. 40 (2009): 696.

[78] For more details on Indonesia's suspension of sample sharing, see Simone Vezzani, "Preliminary Remarks on the Envisaged World Health Organization Pandemic Influenza Preparedness Framework for the Sharing of Viruses and Access to Vaccines and Other Benefits," The Journal of World Intellectual Property. 13.6 (2010): 675-696.

[79] Eurosurveillance, Agreement on a Pandemic Influenza Preparedness Framework for the Sharing of Viruses and Benefit Sharing. April 21, 2011. accessed March 14, 2012. <http://www.eurosurveillance.org/images/dynamic/EE/V16N16/art19847.pdf>

[80] European Centre for Disease Prevention and Control, Pandemic Influenza Preparedness – Significant Agreement on Sharing of Influenza Viruses Sample and Benefit at a Global Open Ended Working Group (Geneva April 11th-16th). April 20, 2011. accessed February 28, 2012. <http://www.ecdc.europa.eu/en/activities/sciadvice/Lists/ECDC%20Reviews/ECDC_DispForm.aspx?List=512ff74f-77d4-4ad8-b6d6-bf0f23083f30&ID=1064#table> This framework is often hailed as "a landmark in global governance for health, representing the first international agreement on influenza virus and benefit sharing." Lawrence O. Gostin and David P. Fidler, "WHO's Pandemic Influenza

Preparedness Framework: A Milestone in Global Governance," Journal of American Medical Association. 306.2 (July 2011): 201.

[81] Among the developing countries, India has made great progress in setting up world-class vaccine manufacturing companies. Several companies like Serum Institute of India, Shana Biotech made significant progress in vaccine development and production. See, Joe Matthew "Vaccine Makers Give India Shot in the Arm," Business Standard. March 28, 2012. accessed on March 29, 2012, <http://www.business-standard.com/taketwo/news/vaccine-makers-give-india-shot-inarm/469277/>

[82] The issue of jurisdiction is a very sensitive problem for global governance, especially in global health issues. Indonesia suspended sample sharing based on sovereignty excuse. Besides sovereignty issue, global health can be compromised since WHO do not have regulative authority on many cases, such as regulation and use of antibiotic in national level. Due to poor regulations and week verification, people in India has access to 3rd level antibiotics. This led to the emergence of 'Super Bug.' However, it would be very challenging for WHO to take initial steps, pressing India to improve its national health regulation.

[83] Kofi Annan. "Problems without Passports," *Foreign Policy*, September 1, 2002. Accessed June 1, 2013. <http://www.foreignpolicy.com/articles/2002/09/01/problems_without_passports>

[84] Colin McInnes et al. "Introduction: Framing Global health," Global Public Health, 7.S2 (2012): S83-S94.

[85] Thomas Abraham. "The Chronicle of a Disease Foretold: Pandemic H1N1 and the Construction of a Global Health Security Threat," *Political Studies*, 59 (2011): 797-812.

[86] Stefan Elbe. "Pandemics on the Radar Screen: Health Security, Infectious Disease and the Medicalisation of Insecurity," *Political Studies*, 50 (2011): 848-866.

[87] There are also precedents of government and military cooperation on this issue. A 2010 report by the U.S. Health and Human Services also suggested that the HHS and the Department of Defense should set up Centers for Innovation in Advance Development and Manufacturing for vaccines. Maggie Fox, "Update 2-New US Pandemic Plan Aims to Speed Products," Reuters. August 19, 2010, accessed on January 31, 2012, <http://www.reuters.com/article/2010/08/19/flu-usa-idUSN1923187420100819>; also see, Ministerial Statements of the Fourteenth Ministerial Meeting Global Health Security Initiative. <http://www.ghsi.ca/english/statementitaly2013.asp>

[88] Melinda Moore et. al. "Sustainability of Sub-Regional Disease Surveillance Networks," Global Health Governance. 2 (Spring 2012): 1-2.

[89] Matt McGrath, "Commercial Ebola Vaccine 'unlikely' say Researchers," BBC World Service. August 15, 2012. accessed August 15, 2012. <http://www.bbc.co.uk/news/science-environment-19112510>

[90] It is already the case in the U.S. where recommendations for improvement in pandemic response was not followed through. The 2009 report of the National Biosurveillance Advisory Subcommittee (NBAS) of the CDC identified various shortcomings, which included overlapping and duplicative untested systems without integration, budget deficiency, inadequate workforce and skill development, and utilization problems. This 2011 NBAS report claimed that those recommendations were not implemented even after the 2009 H1N1 outbreak in the US. A research project by the Center for Biosecurity of UPMC further demonstrated similar shortcomings in US biosurveillance as identified by the NBAS report. See, National Biosurveillance Advisory Subcommittee, Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats. (2009), 4, and National Biosurveillance Advisory Subcommittee, Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats: Second Report of the National Biosurveillance Advisory Subcommittee. (2011), 2, and for the research report by UPMC, see Eric S. Toner et al., "Biosurveillance where it happens: State and local capabilities and needs," Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science. 9.4 (2011): 323.

[91] During the SARS outbreak, many patients in China fled the quarantine facilities ignoring the public health measures.

[92] Some governments in Asia already used their military force during the SARS outbreak. However, their role was limited to performing basic public health functions such as temperature monitoring in transit centers and sick patients tracing. Elizabeth M. Prescott, "The Politics of Disease: Governance and Emerging Infections," Global Health Governance. 1.1 (January 2007): 3.

[93] Currently, the U.S. military runs the Global Emerging Infections Surveillance and Response System (GEIS) which is a network of domestic and overseas military research units covering support for surveillance, training, research and appropriate responses to various infectious diseases. However, our suggestion for domestic-overseas and state-non-state actors involvement with military establishment based is on improving and expanding training policies for pandemic response. Zacher, Mark W. and Tania J. Keefe, The Politics of Global Health Governance. (New York: Palgrave Macmillan, 2008), 49; The U.N. also runs the United Nations Civil-Military Coordination Course. However, the content of the course is

inadequate to respond to an emergency of a severe pandemic. Jean-Paul Chretien, "US Military Global Health Engagement since 9/11: Seeking Stability Through Health," Global Health Governance. 4.2 (Spring 2011): 3.

[94] Adam Kamradt-Scott. "The Evolving WHO: Implications for Global Health Security," Global Public Health, 6.8 (2011): 801-813.

[95] Similar cooperation is noted by the U.S. Homeland Security. However, there is no information available on the follow-up of its implementation. U.S. Homeland Security Council. National Strategy for Pandemic Influenza Implementation Plan, (Washington, 2006), 54-55. Also, the U.S. military runs five laboratories in Egypt, Kenya, Thailand, Indonesia and Peru. However, there activities are limited, with no involvement in surveillance.

[96] Coker and Mounier-Jack write, "The next pandemic will test notions of global solidarity." R. Coker and S. Mounier-Jack, "Pandemic Influenza Preparedness in the Asia-Pacific Region," Lancet. 368 (2006): 886-889.

[97] Simon Rushton, "Global Health Security: Security for Whom? Security from What?" Political Studies, 59 (2011): 779-796.

[98] A. Kamradt-Scott and C. McInnes, "The Securitisation of Pandemic Influenza: Framing, Security and Public Policy," *Global Public Health*, 7.2 (2012): S95-S110.

[99] That is not to say that the world needs EID outbreaks more frequently. The point is that the governance should not lapse in its commitment since such severe outbreak can happen anytime.

Drug Safety and Corporate Governance

Kathy Moscou, Jillian Clare Kohler, and Joel Lexchin

Pharmacovigilance in low and lower middle-income countries has not been commensurate with increasing access to medicines, despite growing recognition that it is important to health outcomes. Pharmacovigilance is impeded where healthcare systems are overburdened and under-resourced. In countries such as India, the population is increasingly exposed to potential adverse drug reactions. Pharmaceutical industry corporate governance, that advances pharmacovigilance in under-resourced countries, would support postmarket drug safety. An analytic framework is used to guide this comparative analysis of pharmacovigilance governance within global pharmaceutical corporations (GPCs) and their Indian subsidiaries. Findings reveal that pharmacovigilance is not fully integrated into corporate governance of the GPCs studied. GPCs exhibiting the least integration have more outstanding drug safety issues. Policy incentives would advance integration of corporate governance and pharmacovigilance.

INTRODUCTION

There is growing recognition that pharmacovigilance matters for health outcomes. Pharmacovigilance is defined as activities to detect, assess, understand and prevent adverse drug effects and drug-related problems. Adverse drug reactions (ADRs) remain among the top 10 causes of death globally and an estimated 2 to 4 million serious, disabling or fatal injuries in the United States (US) are attributable to ADRs annually.[1,2]

Pharmacovigilance in low and lower middle-income (LMI) countries such as India, is more hindered than in developed countries, by poverty and an overburdened, under-resourced health care system.[3] It has not kept pace with increasing access to medicines.[4,5] In a study of two teaching hospitals in India, it was found that more than 32% of elderly patients experienced ADRs.[6] The 2012 Access to Medicine Index (AMI) ranking of the twenty largest global pharmaceutical corporations (GPCs), by their actions to improve access to medicine in developing countries, found that gains have been made.[78] The AMI report also found that, "Overall companies show an apparent lack of willingness to engage in building national pharmacovigilance systems in developing countries."[9] Despite greater access to medicines that treat AIDS, malaria, tuberculosis (TB) and chronic disease, knowledge about their use in patients with comorbid disease (e.g., TB and AIDS) and tropical diseases (e.g., TB and malaria), not endemic in the countries where drug clinical trials have been conducted, is limited.[10] Millions worldwide, receiving antiretroviral, antimalarial, anti-tuberculosis and other medicines, are at increased risk for serious, disabling or fatal ADRs.[11,12] Evidence for real-world effectiveness and safety of fixed dose combination (FDC) medicines is incomplete. Up to 44% of India's top selling medicines are FDCs, and the rationale and safety of 294 FDCs has been questioned by India's Ministry of Health.[13,14]

The primary method for collecting information about ADRs globally is spontaneous reporting, a passive method for detecting drug safety issues. A study of

ADR reporting in low-income countries found that fewer than 2% of ADRs associated with antimalarial drugs were spontaneously submitted over a 40-year period.[15] The ADR reporting rate in India is 1%, despite the recent establishment of 40 ADR monitoring centers and 140 medical college reporting centers.[16]

Compliance with pharmacovigilance regulations has been low in some developing countries.[17] Endemic corruption, as one example, in emerging economies may de-incentivize regulatory compliance.[18] India's largest producer of pharmaceuticals for domestic use and export was sanctioned by the US Food and Drug Administration (FDA) for submitting fraudulent data regarding drug stability for several products manufactured at one of its facilities.[19] The consent decree signed between Ranbaxy and the US Department of Justice on behalf of the FDA in 2012 enforces external audits and other remedies for five years.[20]

Corporate governance, the process of setting and monitoring business goals and strategies by the board of trustees, directors, and shareholders, that advances pharmacovigilance in under-resourced countries would support postmarket drug safety. Maennl (2008) posited that effective pharmacovigilance requires a corporate culture that aligns safety and risk management with corporate business strategy. Misaligned priorities between responsibility to shareholders and corporate social responsibility (CSR) may create tensions that impede pharmacovigilance.[21]

Our paper examines the integration of pharmacovigilance into broader corporate governance policies of GPCs (multinational entities that operate across national boundaries). We further examine the commitment of GPCs to pharmacovigilance internationally and in India, a lower-middle income country with a domestic pharmaceutical industry.

METHODS

Our research investigates six of the top ten pharmaceutical corporations internationally (Abbott Laboratories, Eli Lilly and Company, GlaxoSmithKline, Merck & Co, Novartis Group, and Pfizer Inc.) and their Indian subsidiaries. The GPCs researched reported the highest revenues for pharmaceutical corporations in 2011-2012.[22],[23],[24] Qualitative research methods that included a document and thematic analysis of corporate annual reports, CSR reports, corporate websites, and publicly available FDA, European Medicines Agency (EMA), and the Indian Ministry of Health and Family Welfare documents were used. The data was read and reread in an iterative process. Data was coded using an open coding process. A codebook was created with operational definitions for codes to check coder reliability and reproducibility of the categories (Appendix 1). Themes that explain how postmarket drug safety is integrated into GPC corporate governance were identified. An analytic framework was developed to guide the comparative analysis of pharmacovigilance governance of GPCs (Table 1). GPCs were compared in the following categories: (i) Pharmacovigilance is described as a corporate value, (ii) Pharmacovigilance flow chart or safety framework is published, (iii) Position on pharmacovigilance is publicly available, (iv) Drug safety practices are described as a CSR or in terms of Global Citizenship, (v) GPC participates in extramural pharmacovigilance activities (i.e., contributes to pharmacovigilance activities led by actors external to the company), (vi) GPC complies with regulatory reporting requirements, (vii) Postmarket drug safety is described as a threat, (viii) Action has been

Table 1: Corporate Governance and Pharmacovigilance Framework

	Pharmaco-vigilance described as a corporate value	Pharmaco-vigilance flow chart published	Pharmaco-vigilance position papers posted on website	Drug safety practice is a Global Citizen or a CSR	Partici-pates in extra-mural pharmaco-vigilance activities	Complies with regulator reporting require-ments	Post market drug safety require-ments described as a 'threat'	Actions taken against company for safety issues with drug products	Pending or un-initiated post-market require-ments	Pharmaco-vigilance or drug safety no described in 2010 Annual Report
Eli Lilly	X		X	X		X			X	
Abbott/ AbbVie				X	X	X	X	X	X	
Merck			X		X	X	X	X	XX	
Glaxo Smith Kline			X		X	X	X	X	XXX	
Novartis					X	X	X	X	XXX	
Pfizer			X		X	X	X	X	XXX	X

Pending or uninitiated postmarket requirements: X= Fewer than 15% of PMR studies are pending or uninitiated , XX= PMR studies pending or uninitiated are greater than 15% and less than 50% , XXX= More that 50% of PMR requirements are pending or uninitiated.

taken against the corporation for drug safety issues (s), (ix) Pending or uninitiated postmarket requirements (PMR), and (x) Pharmacovigilance or drug safety is not described in the corporate annual report. Using the analytic framework, consistency between corporate statements and actions was compared to aid in the analysis of corporate governance and commitment to pharmacovigilance. GPCs were categorized into four tiers, using the analytic framework and based on the publicly available sources outlined in the methodology (Table 2).Unless otherwise stated, references made are attributed to the parent company, not the Indian subsidiary.

Table 2: Criteria for Classification of Global Pharmaceutical Corporations

Tier 1	Tier 2	Tier 3	Tier 4
≥ 3 corporate values that are characteristic of pharmacovigilance governance[a] *and* drug safety practices described as CSR or Global Citizenship	≤ 3 corporate values that are characteristic of pharmacovigilance governance *and* drug safety practices described as CSR or Global Citizenship *and* Postmarket drug safety requirements described as a 'threat'	≤ 3 corporate values that are characteristic of pharmacovigilance governance *and* 3 corporate values *not* characteristic of pharmacovigilance governance[b] *and* > 15% PMR requirements pending or uninitiated	≤ 2 corporate values that are characteristic of pharmacovigilance governance *or* ≥ 3 corporate values *not* characteristics of pharmacovigilance governance *and* > 50% PMR requirements pending or uninitiated

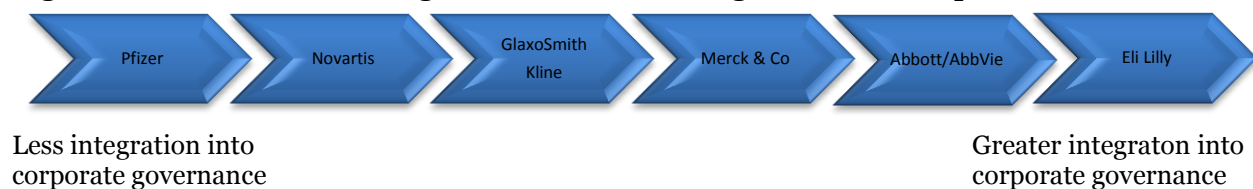[a] Corporate values characteristic of pharmacovigilance governance: Pharmacovilance is described as a corporate value, Pharmacovigilance flow chart or safety framework is published, Pharmacovigilance position is publically available, Drug safety practices are described as a Corporate Social Responsibility or in terms of Global Citizenship, Company participates in extramural pharmacovigilance activities, Company complies with regulatory reporting requirements.

[b] Corporate values *not* characteristic of pharmacovigilance governance: Post-market drug safety is described as a threat, Action has been taken against the corporation due to safety issues with drug product(s), Pending or uninitiated postmarket requirements, Pharmacovigilance or drug safety is not described in the corporate annual report.

RESULTS

Our research found variation in integration of pharmacovigilance and corporate governance among the companies analyzed, which falls along a continuum (Figure 1). Differences were also found between each parent company and their Indian subsidiary, except where the subsidiary claimed to have adopted all of the parent company policies (e.g., Merck India).

Figure 1: Continuum for Integration of Pharmacovigilance into Corporate Governance

| Pfizer | Novartis | GlaxoSmith Kline | Merck & Co | Abbott/AbbVie | Eli Lilly |

Less integration into corporate governance

Greater integraton into corporate governance

PHARMACOVIGILANCE AS A CORPORATE VALUE

Eli Lilly

Eli Lilly ranked highest in integration of pharmacovigilance and corporate governance and is the only company in tier 1. Postmarket drug safety is described as a CSR and safety monitoring is shown as a core area in Lilly's integrated global quality system diagram.[25] Pharmacovigilance is described in three separate sections of its CSR report.[26] The Lilly Bioethics Program governs research and development (R&D) and is headed by the vice president of Global Patient Safety and Bioethics. R&D is characterized in the CSR report as a 7-stage process that begins with drug discovery and concludes with postmarket testing.[27] Lilly's Global Patient Safety Organization (GPSO)

network of physicians, pharmacists, nurses and other healthcare providers monitors, collects, evaluates and reports information pertaining to product safety. The GPSO's mandate is to, "report adverse events and continuously monitor the safety of Lilly's products through their entire life cycle, including the identification of changes in the benefit/risk balance."[28] The Public Policy and Compliance Committee terms of reference that requires annual review of the effectiveness of Lilly's compliance program in meeting FDA and other US federal health care program requirements, including pharmacovigilance, provides further evidence for integration of corporate governance and drug safety.[29] The Eli Lilly (India) website claims that corporate governance is guided by company values for integrity, respect for people, and excellence.[30] It is the only Indian subsidiary that provides information about adverse drug reactions and a link for ADR reporting on its homepage. Corporate accountability, however, is built on "clear, consistent, and truthful communication about [our] performance", and is framed in the context of investor confidence rather than patient safety and pharmacovigilance.[31]

Abbott

Abbott and the independent biopharmaceutical spin off company AbbVie are ranked in tier 2. The companies describe drug safety as a CSR, participate in extramural pharmacovigilance activities and comply with regulatory reporting. Their websites claim that they prioritize patient safety, product safety and integrity.[32] Patient safety is linked to CSR.[33] Citing the importance of regulatory compliance in protecting public health, AbbVie reports that it upholds 'the letter and spirit of healthcare laws... complies with all legal and regulatory requirements that govern the reporting of safety information to regulatory or public health agencies and communicate[s] with each government agency that oversees our products to address potential safety concerns' in its business code of conduct.[34] In contrast to statements reported in its code of conduct, AbbVie states that regulatory compliance cannot be guaranteed in its Security and Exchange Commission (SEC) 10K report.[35] AbbVie and Abbott describe counterfeit medicines and products diverted from the legal supply chain as drug safety threats rather than ADRs.[36,37]

Abbott and AbbVie report the status of clinical trials (premarket and postmarket) and list postmarket commitments on their websites.[38,39] Abbott publishes this information on its Global Citizen webpage, supporting its claim of commitment to transparency.[40]

In contrast, Abbott India states that its philosophy of corporate governance is to protect the company, be accountable to shareholders and conduct business ethically and transparently.[41] In its 2010 annual report, Abbott India describes counterfeit drugs as a risk to company profit rather than to patient safety.[42] Abbott India continued to market Leptos (sibutramine) until it was banned by India's Ministry of Health and Family Welfare, one year after it was withdrawn from European Union (EU) and US markets.[43] Phenylpropanolamine (PPA) continues to be marketed by Abbott in India despite an FDA request that 'all drug companies discontinue marketing products containing PPA' in the US.[44]

Merck

Merck is ranked in tier 3 of our continuum. The company addresses pharmacovigilance governance on its website, participates in extramural pharmacovigilance activities and complies with regulatory reporting. The executive vice president and president of Merck Research Laboratories (MRL) are responsible for Merck's global pharmacovigilance strategy.[45] MRL safety teams evaluate the safety of medicines and vaccines.[46] Merck's Global Compliance Organization periodically audits global pharmacovigilance practices for compliance with regulations and guidelines.[47] Risk Management & Safety (RMS) teams 'assess patient safety using product labeling, physician and patient educational programs, and other risk-minimization strategies' and 'implement strategies to determine the effectiveness of these interventions, as appropriate'.[48]

Pursuant to *Fagin v. Scolnick* (2010), the class action suit involving Vioxx (rofecoxib), Merck has made corporate governance changes to create a product safety committee. However, details about the committee are not posted on the company website. Merck also added pharmacovigilance topics to its Code of Conduct as required, which in aggregate comprise approximately one of forty-three pages. Topics covered pertain to post-authorization safety studies (e.g., ethics questions regarding inappropriate promotion of observational studies in order to increase sales) and reporting ADRs even when mentioned in an informal setting.[49] Selective reporting of study results is denounced however a limitation on dissemination and publication of the results persists. Merck's Code of Conduct states, "As a researcher, before you consider releasing any scientific result or information that is based on work conducted at Merck/MSD, you are required to first seek the approval of your divisional vice president, or have the information reviewed by the Office of Scientific and Technical Information Clearance process for approval."[50] This has implications for identifying and publicly reporting early signals of safety issues and risk communication. Merck proclaims it is committed to timely registering, conducting and reporting of clinical trial results,[51] however, it was issued a warning by the FDA in 2012 for failing to meet the agreed upon timetable for completion of required postmarket studies.[52] Merck also claims to have integrated CSR into its governance and business strategy, and has established the Office of Corporate Responsibility, the Public Policy and Responsibility Council and the Corporate Responsibility Report Working Group (external stakeholders) to develop and monitor CSR targets and performance indicators. However, Merck defines corporate citizenship as being committed to complying with laws and regulations governing the way they market and sell medicines and other products, and does not specifically address pharmacovigilance.[53,54]

The Merck India website claims that it is committed to patient safety, maintains an Adverse Event Reporting database and follows procedures for safety monitoring and compiling information about adverse events (ADEs) in compliance with global regulations.[55] The link to information directs the viewer to the Merck parent company website. Ethics and transparency are a corporate value according to Merck India, yet Merck continued marketing Vioxx in India one year after the drug was withdrawn in US and EU markets and continues to include PPA in Indian cold products.[56] Although PPA-containing products were banned in India in 2011, the ban was stayed by the High Court of Madras, India as a result of a successful challenge by CIPLA, an Indian company.[57]

GlaxoSmithKline

GlaxoSmithKline (GSK) is also ranked in tier 3. Characteristics of integration of pharmacovigilance into corporate governance that were identified are a publicly accessible pharmacovigilance policy, participation in extramural pharmacovigilance activities and compliance with reporting requirements.

GSK's policy on pharmacovigilance is outlined in a position paper on its website.[58] It supports the European Federation of Pharmaceutical Industries and Associations (EFPIA) harmonization directive that 'no additional national requirements will be allowed unless justifiable for pharmacovigilance reasons'.[59] Pharmacovigilance is incorporated into GSK's Global Safety Board mission to 'ensure that human safety is addressed proactively throughout product development and to review the safety of GSK Products as may be warranted in light of clinical experience'.[60] This value is contrasted with GSK India's statement on Research & Development and Regulatory Matters which states that 'Efforts towards ensuring a speedy review and approval by regulatory authorities... will help achieve early access to new and innovative therapeutic options to patients in the country'.[61] GSK India's annual report 2011-12 states that corporate governance is 'guided by a strong emphasis on transparency, accountability and integrity... codified [in a] Corporate Governance Charter, which is in line with the best practice,... meets all the relevant legal and regulatory requirements'.[62] Yet, GSK India does not explain the nature of the seven consumer cases pending against the company.[63] The GSK India postmarket drug safety philosophy is not stated in its annual report, however, its commitment to protecting the rights and safety of patients in drug studies is stated.[64] GSK's standard for clinical trials in developing countries, posted on the parent company website, is that comparator drugs used in drug trials will never be less beneficial than the local standard of care. Though, the drugs may be less beneficial than the 'best current treatment available anywhere in the world'.[65] This is unlike trials that might be conducted in developed countries.

Novartis

Novartis is ranked in tier 4 of our continuum. The R&D process is described as concluding with market approval and information about postmarket drug safety is limited in its annual report.[66,67] Novartis alludes to post-approval commitments by describing its requirement to conduct a Phase IV study of Gilenya (fingolimod), a drug used in the treatment of multiple sclerosis.[68] In the Novartis 2010 and 2012 annual reports, sections titled "Increasingly challenging business environment" and "Increasing regulatory and safety hurdles", the company decries that, "...post-approval regulatory burden on pharmaceutical companies has also been growing[69]... and further heighten the risk of recalls, product withdrawals, or loss of market share."[70] In summarizing its corporate citizenship in 2010, Novartis reports, "engaging with society to improve healthcare... access-to-medicine [and] ...R&D institutes for diseases in developing countries, [and] ...USD $1.5 billion or 3% of net sales."[71] By linking sales goals to increasing access to medicine, it can be inferred that the company's interest in R&D in developing countries is motivated by projected sales. As developing countries begin to strengthen their pharmacovigilance systems and impose greater regulatory

requirements for postmarket drug safety, it is unclear whether Novartis will find this to be a disincentive to continued R&D for diseases endemic to developing countries.

The Novartis India annual report describes corporate citizenship as meeting, "the expectations of stakeholders …and rules concerning ethical business conduct."[72] In prioritizing responsibility to shareholders Novartis India shows that a culture for drug safety is not well integrated into corporate governance. Whereas the importance of patent protection is described in five pages of the Novartis India annual report, there is no description of pharmacovigilance policies or drug safety.[73]

Pfizer

Pfizer illustrates the least integration of pharmacovigilance governance and is also placed in tier 4. Despite statements in its 2010 annual report that "Patient safety is our absolute first priority", Pfizer's 2010 and 2012 global financial reports tell a different story about corporate values and drug safety.[74] Pfizer was the only company that did not include information about pharmacovigilance in its 2010 annual report. Drug safety was described in the context of potential risks to its projected financial outlook and litigation.[75,76] The company has included two references in its 2012 annual report pertaining to PMRs for product life cycle monitoring and postmarket studies.[77] Pfizer has been delinquent in meeting its postmarket commitments and has received warning letters from the FDA.[78] Pfizer's activities to support pharmacovigilance are not highlighted in its annual report. In contrast, company activities to increase access to Pfizer products in emerging markets through its 30 programs and partnerships are highlighted.[79]

Pfizer India claims to have adopted the corporate values of its parent company: integrity, respect for people, customer focus, community, innovation, collaboration, performance, leadership, and quality. None of the core values are directly related to drug safety. The only reference to pharmacovigilance cited in the Pfizer India annual report is the Medical Affairs and Research Division which, "… provides medical support to regulatory registration as well as safety review and labeling activities."[80] Pfizer India states that, "…recent regulatory uncertainties like the proposed new drug policy coupled with the policy paralysis and economic downturn could cripple the growth curve."[81] The drug policy the company deems unfavorable is not specified.

PUBLIC ACCESSIBILITY TO PHARMACOVIGILANCE FLOW CHART AND POSITION PAPERS

Public accessibility to information about pharmacovigilance and drug safety is limited for GPC Indian subsidiaries. Abbott India describes drug safety relative to counterfeit drugs. Merck's and Pfizer's Indian subsidiaries reference their parent company policies. The Eli Lilly (India) website provides the most information pertaining to pharmacovigilance. Their Patient Safety webpage describes the physician and patient responsibility to report adverse drug reactions and Lilly's role to continue monitoring the safety of medicines even after the drug reaches the market.[82] The company states that "Safety Information is continually assessed and we share new findings and emerging concerns openly with regulators and physicians to appropriately manage risks associated with the use of our medicines".[83] A banner across the bottom of the Eli Lilly

(India) homepage informs visitors to the website about reporting adverse events and complaints about Lilly products.[84] The Eli Lilly (India) Patient Safety web page provides a direct link to India's Drug Controller General of India (DCGI) national pharmacovigilance program to report adverse drug reactions.[85]

The parent company's position on pharmacovigilance is more widely accessible on its Headquarters' website. Abundant information explaining pharmacovigilance and Lilly's role in postmarket safety is posted to its Patient Safety website. The documents are written in lay language and describe the role of the company, patient, healthcare provider, and the FDA for patient safety.[86] The website describes postmarket studies and spontaneous reporting as sources of information for emerging safety issues. Lilly does not state how or why decisions are made to conduct postmarket studies and only states that data collected through studies and spontaneous reporting is reviewed periodically, without giving the frequency.[87] If a safety issue arises, the company's risk management program includes risk communication to physicians, health regulators, and patients (e.g., Dear Health Professional letter). Voluntary market withdrawal of the product, as a possible outcome of a newly discovered safety issue, is not mentioned on this webpage. Product withdrawal is cited as an outcome of unexpected safety concerns in Lilly's annual report.[88]

GSK's position on pharmacovigilance is posted on its website in a policy statement that claims the corporation is committed to placing patient interests above corporate interests and to monitoring the safety profile of a drug throughout the product life cycle.[89] GSK's description of postmarket drug safety as a threat in its annual report, and support for EFPIA's limits on regulation, is inconsistent with statements about patient interests.[90,91]

Abbott's strategy for addressing drug safety is briefly described on its webpage entitled Global Citizenship.[92]Abbott claims that it investigates drug safety signals and acts in accordance with established corrective and preventative action plans. The plans are not published on its website, despite corporate governance statements about commitment to transparency.

Merck's position statements on pharmacovigilance are found on the Patient Safety page of its website. The role of its RMS teams in monitoring safety issues throughout the product life cycle and in the development of Risk Management Plans is described.[93]

EXTRAMURAL PHARMACOVIGILANCE ACTIVITIES

Novartis, Pfizer, Merck, Abbott and GSK are partners in the International Serious Adverse Event Consortium (iSAEC). The iSAEC is a consortium of corporate, scientific, and commercial partners that includes government regulatory authorities (e.g., FDA, EMA), US Veterans Administration, universities, private and public research networks (e.g., Wellcome Trust, Dundee University, and HMO Research Network).[94] The consortium pools data on serious adverse events (SAE) and analyzes it to identify genetic markers of risks for rare SAEs (e.g., acute hypersensitivity syndrome).[95] Eli Lilly is the only GPC studied that is not a member. GSK is the deputy coordinator of the **P**harmacoepidemiological **R**esearch on **O**utcomes of **T**herapeutics by a **E**uropean **C**onsortium.[96,97]

REGULATORY COMPLIANCE

Pharmaceutical manufacturers are required to collect information about ADRs and submit a Periodic Safety and Update Report annually (PSUR) to the FDA. According to draft guidelines, a serious adverse event that occurs during clinical trials must also be reported to India's regulatory authority.[98] Abbott claims to comply with reporting requirements but does not provide specific details on its website. Eli Lilly provides information about Risk Management Plan (RMP) requirements and claims to submit a RMP with each new drug application. RMPs are described as proactive and systematic activities designed to identify, characterize, minimize, and communicate product risks rather than a regulatory burden.[99] Merck claims to follow local laws and practices for ADR reporting outside the US.[100] This may place patients at risk for unnecessary exposure to known ADRs in countries e.g., India, where reporting requirements are more lax. One year after Vioxx was withdrawn from the US market, a warning still had not been issued in India.[101] In contrast, AbbVie claims to follow the higher regulatory requirement and laws where country differences exist.[102]

Merck states that PMRs for US marketed products are posted on its website quarterly, as required by US FDA regulations. PMRs may include clinical, non-clinical, and pharmacovigilance studies/trials.[103] The web link to more information directs the reader to the FDA's website for a description of PMR requirements rather than linking to Merck's quarterly report. Merck was issued a warning letter on February 17, 2012 by the FDA regarding the company's failure to complete postmarket studies for Januvia (sitagliptin) and Janumet (sitagliptin and metformin), required as a condition for market approval in 2010.[104] Merck must now meet a revised timetable for the studies or face regulatory actions by the FDA, including but not limited to, civil or monetary penalties. The studies' status for meeting the revised timetable is unavailable. Pfizer also received a warning letter from the FDA in 2010 regarding its failure to submit reports of adverse events within required timeframes.[105]

POSTMARKET DRUG SAFETY REQUIREMENT AS A "THREAT"

Increasing regulatory scrutiny and PMRs are described as a business threat in Merck, Pfizer, GlaxoSmithKline, Novartis, Abbott and AbbVie annual reports. Regulatory discretion to require postmarket Phase IV trials or other studies, re-review of drug safety and effectiveness of marketed products in the US and EU, and changing public and government expectations for safety and efficacy, are cited as risks to the demand for Merck products.[106] Clinical trials and postmarket surveillance of marketed drugs that lead to recalls, increased scrutiny, concerns by prescribers and patients, government action and litigation (civil and criminal) are predicted to continue, further exposing the pharmaceutical industry and Merck to risk, according to Merck annual report statements.[107]

For example, GSK's 2012 annual report states:

> ...emerging markets have been increasing their regulatory expectations based on their own national interpretations of US and EU standards. Stricter regulatory controls heighten the risk of changes in product profile or withdrawal by regulators on the basis of post-approval concerns over product safety, which

could reduce revenues and result in product recalls and product liability lawsuits.[108]

The statement is inconsistent with website claims valuing patient interests above corporate interests. Pharmacovigilance is not listed as a GSK strategic priority.

Novartis' corporate literature describes postmarket drug safety as a threat. The company received FDA warning letters regarding several of its drugs between 2010-2013, for failure to cite risks for use in product advertising, including Gleevec (imatinab), Tasigna (nilotinib), and Exforge (amlodipine + valsartan).[109] Zelnorm (tesagerod) was available in India in 2011, nearly four years after it was withdrawn from the market in the US and European countries.[110] A parliamentary standing committee in India reported that Novartis submitted clinical trial results for approval of aliskeran, in which only 46 out of the required 100 patients were enrolled.[111]

Increasing regulatory scrutiny is described as a risk to financial targets in both Pfizer parent company and Pfizer India's 2012 annual reports.[112,113] The Pfizer India annual report claims that regulatory uncertainties and a proposed new drug policy could *cripple* growth, although the report does not identify the specific policy.[114]

Compliance with FDA, international and supranational regulatory requirements for postmarket studies and other post-approval regulatory requirements, according to statements in Abbott and AbbVie's 2013 annual reports, "is costly and materially affects Abbott's business... health care regulations substantially increase the time, difficulty, and costs...obtaining and maintaining approval to market...products.", [115,116] The 2012 AbbVie annual report asserts that postmarket studies may find new safety or efficacy issues that could halt sales or reduce market acceptance of its products.[117] Neither Abbott nor AbbVie guarantees that regulatory compliance will be maintained once product approval has been obtained, including postmarket pharmacovigilance and adverse event reporting.[118,119]

Noticeably absent from Lilly's annual report is a characterization of pharmacovigilance and drug regulatory requirements as a threat to the company's business. The company acknowledges that, "Unexpected safety or efficacy concerns can arise with respect to marketed products, leading to product recalls, withdrawals, or declining revenue, as well as costly product liability claims."[120] This single negative reference to postmarket drug safety in the annual report is characterized as the nature of the pharmaceutical industry.

ACTIONS TAKEN AGAINST THE CORPORATION FOR SAFETY ISSUES

The New Jersey Superior Court settlement related to Vioxx in *Fagin v Scolnick (2010),* which required Merck to create a product safety committee, also required it to register all clinical trials, submit results to the clinical trial registry (clinicaltrials.gov), and accurately report all study results in compliance with the FDA Amendment Act 2007.[121] Despite the settlement, Merck was issued an FDA warning in 2012 for failing to meet the agreed upon timetable for completion of postmarket safety studies for Januvia and Janumet.

Pfizer reported that it received an FDA warning in its 2010 annual report, "with respect to the reporting of certain post-marketing adverse events relating to certain drugs."[122] The warning letter sent to Pfizer, posted on the FDA website, admonished

Pfizer for failing to submit reports of serious unexpected adverse drug reactions (SUSARs) for five drugs; two were the Pfizer blockbusters Lipitor (atorvastatin) and Viagra (sildenafil).[123] In the case of Viagra, the FDA claimed that the company misclassified the ADR as non-serious to avoid increased requirements for reporting SUSARs.[124] The FDA admonished Pfizer for a decline in timely reporting of adverse drug events between 2008 and 2009.[125]

POSTMARKET REQUIREMENTS

All of the companies were required by the FDA to conduct postmarket studies for select drugs (Figure 2). As of June 2013, Abbott had submitted the final report to the FDA for its one required PMR.[126] Eli Lilly was issued twenty-two PMRs for six drugs. Nine studies are ongoing, and the final report was submitted for ten studies. Three studies have not been initiated, however, according to FDA classification, these have not met formal requirements for delay (i.e., the original projected date for initiation of patient accrual or initiation of animal dosing has not passed).[127] A total of seventy PMRs were

Figure 2: Summary of Postmarket Requirements (PMR) 2010-2013*
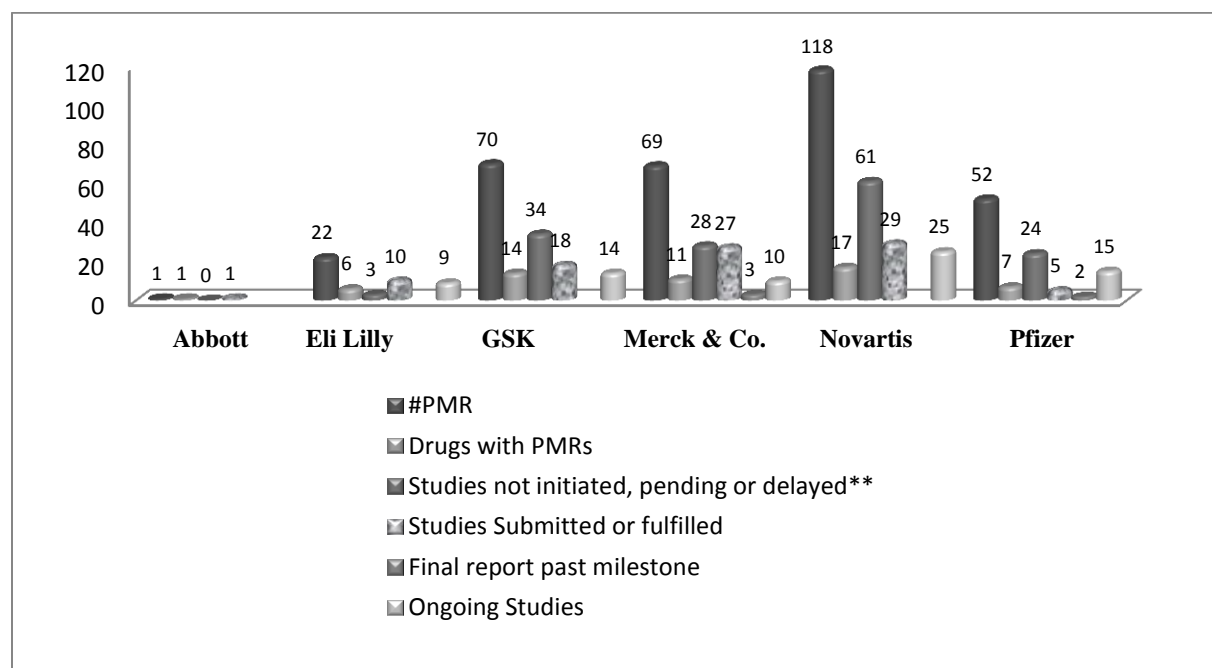
*Source: FDA "Postmarket Requirements and Commitments".
www.accessdata.fda.gov/scripts/cder/pmc/index.cfm

issued to GSK for fourteen drugs and seventeen vaccines. The FDA canceled four PMRs. Of the remaining sixty-six, thirty-four studies are uninitiated (no explanation has been provided for six pending PMRs), fourteen studies are ongoing, and eighteen have been completed with reports submitted.[128] One of the pending studies was required in 2008.[129] Merck had sixty-nine PMRs for eleven drugs and eight vaccines. As of June 2013, twenty-eight studies were pending, twenty-seven completed, and ten were ongoing.[130] One hundred eighteen PMRs were issued to Novartis for seventeen drugs

and twenty vaccines.[131]   The FDA canceled the PMRs for Zelnorm: the drug was withdrawn from the market. Of the remaining PMRs, sixty-one are uninitiated, twenty-five studies are ongoing, and twenty-nine have been completed with reports submitted.[132] The completion date for one of the delayed studies was originally set for 2009.[133] Pfizer was issued fifty-two PMRs for seven drugs. The company has fifteen studies ongoing, submitted the final report for five, and twenty-four studies are uninitiated.[134] Additional data are given in Appendix 2.

DISCUSSION

We found that corporate governance has clear implications for pharmacovigilance. Values promoting drug safety begin in the boardroom, yet tensions between corporate responsibility to shareholders and CSR to a broader range of stakeholders may impede a culture of pharmacovigilance.[135,136]   Maennl (2008), found that effective corporate pharmacovigilance requires a culture of safety that aligns safety and risk management with corporate business strategy. This culture does not exist in most pharmaceutical companies, a finding supported by our research.[137]

Although the company documents analyzed claimed that each GPC was working to achieve Millennium Development Goals (MDGs) to increase access to medicines, their commitment to pharmacovigilance was not found to be commensurate. Nearly all of the companies included in our study received low AMI ratings for their efforts to strengthen national pharmacovigilance systems.[138] Postmarket drug safety in low and LMI countries such as India is further compromised when corporate governance that advances pharmacovigilance is absent, and healthcare system resources and pharmacovigilance capacity are limited.[139]

GPCS AND POSTMARKET DRUG SAFETY IN INDIA

India's population increasingly has access to new and older pharmaceuticals.[140] However, the population is vulnerable to adverse effects linked to brand name and generic pharmaceuticals voluntarily withdrawn by GPCs in other countries. As recently as April 2013, a parliamentary standing committee on health charged the government with procrastination in following through with a pledge made to suspend market authorization for all drugs prohibited for sale in the US, Canada, EU, Australia and other countries and accused the ministry of, "collusion with the intention to save the guilty."[141] It was not until June 2013 that India's Ministry of Health and Family Welfare took action to ban the analgesic Analgin (metamizole), the antidepressant Deanxit (flupentixol + melitracene), and the generic antidiabetic pioglitazone.[142,143,144] All three drugs, produced by GPCs (Sanofi, Sanofi India and Lundbeck Italy), including generic pioglitazone, had been banned in other countries years earlier.[145] Tesagerod, withdrawn by the FDA in 2007, and not banned in India until 2011, was found on drug outlet shelves in June 2011 during a Drugs Controller General of India (DCGI) inspection.[146] Without a fulltime drug controller general since 2012, the DCGI's capacity to monitor pharmacovigilance compliance has been limited.[147] A survey of 230 Delhi pharmacists, community, hospital and medical representatives (from thirty-three GPCs including Eli Lilly, Pfizer, Aventis, GSK, and Astra Zeneca), assessed the knowledge, skills and attitudes about pharmacovigilance and ADR reporting. It found that medical

representatives had the least awareness of pharmacovigilance (35.48%), and only 14.51% of the medical representatives claimed they had ever reported ADRs despite Central Drugs Standard Control Organization guidelines that all ADRs should be reported.[148]

PHARMACOVIGILANCE AND CORPORATE GOVERNANCE: DIVERGENT STANDARDS

Our research found GPC's had divergent integration of pharmacovigilance and corporate governance. Parent company and Indian subsidiary standards also diverged. Abbott, Merck, Novartis, and Pfizer's publically stated positions on regulatory requirements differed from SEC filings. GPC's characterization of regulations requiring 1) postmarket testing, 2) documentation of safety and efficacy, and 3) greater scrutiny of compliance with product manufacture, as *regulatory and safety hurdles* because they can harm the company's reputation, result in product recall, withdrawal or litigation, is an impediment to pharmacovigilance governance. The push for speedy review and regulatory approval for the purpose of early access to markets, as described in GSK India's annual report, is not aligned with the *precautionary principle* which suggests that marketing should be delayed until sufficient safety information is compiled. Rather than strengthening pharmacovigilance regimes in low and LMI countries, as recommended by the AMI, GPC's support for supranational positions (e.g., EFPIA) to limit additional national requirements suggests that they would be unlikely to lead efforts to implement stringent pharmacovigilance strategies.[149,150]

Research findings suggest that a corporate culture of pharmacovigilance is a determinant for PMR completion and the resolution of outstanding product safety issues. Eli Lilly, which comes closest to Maennl's model for corporate culture of pharmacovigilance, had fewer uninitiated or delayed PMRs than Merck, Pfizer, Novartis, and GSK.[151] GSK, Pfizer, and Novartis had the highest level of pending or uninitiated PMRs and the lowest level of study completion. Eli Lilly had a product withdrawn from the US, EU, or Indian market between 2010 and 2013, as did the other GPCs. Abbott and Merck, which described postmarket drug safety regulations as a threat in their corporate annual report, marketed their products in India after the drugs were withdrawn from US or EU markets. They exposed patients in India to medicines for which serious adverse events were known. Abbott India continued to market Leptos (sibutramine) until it was banned in India, one year after it was withdrawn from EU and US markets.[152] Abbott and Merck cold products, reformulated in the US, continue to contain PPA in India. This suggests not only a failure of pharmacovigilance governance but also a double standard for postmarket drug safety in the developing countries, as compared to developed countries. Similarly, GSK has divergent standards for the use of comparator drugs in clinical trials in developing and developed countries.[153] If GSK has divergent standards for clinical trials, it may also have a double standard for drug safety.

Public access to information about pharmacovigilance and drug safety is limited for GPC Indian subsidiaries. Pharmacovigilance is not described in the GSK India or Novartis India annual reports, and Abbott India describes drug safety relative to counterfeit drugs. Merck and Pfizer's Indian subsidiaries reference their parent company policies and do not explicitly discuss corporate governance pertaining to pharmacovigilance. When the link to information about Merck's safety monitoring is clicked, the viewer is directed outside the Merck India website and warned that MSD is

not responsible for the content.[154] Information is posted to the Eli Lilly (India) website. However, the company's corporate annual report is not publicly available to verify internal consistency between stated positions. The lack of public information by GPC Indian subsidiaries has implications for accountability for postmarket drug safety in India.

CONCLUSION

We found an inverse relationship between GPC integration of pharmacovigilance into corporate governance and outstanding product safety issues. The lack of integration has resulted in the perception that postmarket commitments are a threat rather than an opportunity to build value for the company. Our research suggests that the MDGs for access to medicines are insufficient to assure access to safe medicines. The ranking of GPCs for integration of pharmacovigliance and corporate governance varied between our study continuum and the AMI. Whereas Eli Lilly was ranked highest in our research, it was ranked fourteenth in the AMI. A possible explanation could be that pharmacovigilance is but one of the indicators of Capability Advancement in Product Development & Distribution, an area that received only 10% weighting by the Access to Medicine Foundation in the construction of the AMI.[155] Further research is needed to better understand the inverse company ranking.

GPC Indian subsidiaries' integration of drug safety and corporate governance is limited. Pharmacovigilance is unlikely to be supported solely by GPCs without robust policy incentives. Supranational standards requiring GPCs to strengthen capacity for pharmacovigilance in under-resourced areas and exceed minimum standards, as measured by the AMI, would enhance postmarket safety. GPCs currently abide by some supranational standards promoted by the International Conference on Harmonization. Rebates (or fines) based upon meeting (or not meeting) the highest pharmacovigilance standards, when country differences exist, would incentivize GPCs. Incentives that assure that drugs withdrawn from US, European and other major markets do not continue to be marketed in developing countries should be implemented. Employee bonuses based on innovation supporting pharmacovigilance would also incentivize postmarket drug safety.

Corporate governance that strengthens pharmacovigilance and builds capacity to monitor and enforce regulatory compliance will enhance postmarket drug safety and reduce corporate reputational risk related to product safety issues. Independent monitoring by the national drug regulatory authority supported by international regulatory authorities (e.g., FDA and EMA) and global health institutions such as the WHO is recommended to hold GPCs accountable for postmarket drug safety.

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Appendix 1: Corporate Governance Codebook

	Definition	Example
Pharmacovilance described as a corporate value	Postmarket drug safety and safety monitoring is described as integrated within the global quality system and a Corporate social responsibility	*The quality process is fully integrated into each and every stage of drug development: the design phase, the delivery phase and the monitoring phase-* Eli Lilly Corporate Responsibility Report update 2012
Pharmacovigilance flow chart or safety framework published	Flow charts show passive and active pharmacovigilace activities e.g. pharmacosurveillance and postmarket clinical trials	
Pharmacovigilance position publically available	Position papers posted on website	The safety governance framework states that staff is *'required to report immediately any issues relating to the safety or quality of our medicines'.-* GSK Global Public Policy Issues-Position on Pharmacovigilance
Drug safety practices described CSR or Global Citizen	Record of drug safety activities in reported in Annual Corporate Social Responsibility Report or Annual Global Citizenship Report	*Recognizing that all health care products and procedures entail some degree of risk, we are committed to working with a broad range of stakeholders to minimize these potential risks while optimizing opportunities for improved health and well-being'-* Abbott 2010 Global Citizenship Report
Participates in extramural pharmacovigilance activities	Member of external body engaged in improving pharmacovigilance	*It is important that research is undertaken to establish the most effective ways to minimise the risks of medicines including effective ways of communicating the risks and benefits ...The Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium*

		(PROTECT)...is a collaborative European project aimed at addressing the limitations of current methods in the field of pharmacoepidemiology and pharmacovigilance. The EMA is the coordinator of PROTECT and GSK is the deputy coordinator.-GSK position paper on pharmacovigilance (2011)
Complies with regulator reporting requirements	Submits reports of Suspected Unexpected Serious Adverse Reactions (SUSARS) and annual Periodic Safety Update Reports (PSURs).	*[The] country manager is responsible for the collection of safety information and reporting issues in PSURs and discussing proposed action to mitigate risks with regulatory authorities-* GSK Global Public Policy Issues-Position on Pharmacovigilance
Post-market drug safety described as a threat	Regulations requiring post-market safety studies described as a threat to corporate profits due to cost of clinical trials, risk for market withdrawal, or loss of market share.	*The post-approval regulatory burden on pharmaceutical companies has also been growing. ...post-approval Phase IV clinical trials to gather detailed safety and other data on products...further heighten the risk of recalls, product withdrawals, or loss of market share. -* Novartis 2010 Corporate Annual Report *We are confronted by increasing regulatory scrutiny of drug safety and efficacy ... even when we view data as sufficient to support the safety and/or effectiveness of a product candidate or a new indication for an in-line product, regulatory authorities may not share our views and may require additional data or may deny approval altogether. –* Pfizer Annual Report 2010 Appendix A 2010 Financial Report *...emerging markets have been increasing their regulatory expectations based on their own national interpretations of US and EU standards. Stricter regulatory controls heighten the risk of changes in product profile or withdrawal by regulators on the*

		basis of post-approval concerns over product safety, which could reduce revenues and result in product recalls and product liability lawsuits.- GSK 2012
Action taken against corporation due to safety issues with drug product(s)	Product(s) withdrawn, labelling changes required for safety issues, Application Integrity Policy invoked, or litigation filed within past 3 years	*Our businesses have been subject to significant civil litigation as well as governmental investigations and information requests by regulatory authorities*- Novartis 2010 *Beginning in December 2008, purported class actions were filed against us …under Canadian product liability law, including with respect to the safety and efficacy of Champix*– Pfizer Annual Report 2010 Appendix A 2010 Financial Report
Pharmacovigilance or drug safety not described in Annual Report	Description of corporate policies or governance related to pharmacovigilance or drug safety omitted	

Appendix 2: Summary of Postmarket Requirements 2010-2013[a]

	Number of PMR	Drugs with PMRs	Drug Name(s)	Studies not initiated, pending or delayed [b]	Studies Submitted or fulfilled	Final report past milestone	Ongoing Studies	Type of Study
Abbott	1	1	Depakote	0	1			Drug interaction between Depakote + olanzapine
Eli Lilly	22	6	Prozac, Effient, Zyprexa, Forteo, Cymbalta, Symbyax	3	10		9	
GlaxoSmithKline	70[c]	14	Arzerra, Horizant, Altabax, Votrient, Advair diskus, Zofran, Zyban, Potiga, Arixtra, Veramyst, Alli, Promacta,	34	18		14	Flonase and Nicorette studies were released

			Lamictial, Lamictal ODT & CD, Requip XL, (+17 vaccines)					
Merck	69[d]	11	Janumet, Janumet XR, Januvia, Gardasil, Victrelis, Zolinza, Cancidas, Vioxx, Juvisync, Emend, Isentress, Dulera, (+8 vaccines)	28	27	3	10	
Novartis	118[e]	17	TOBI Podhaler, iLaris, Signifor, Reclast, Neoral, Tyzeka, Foradil, Fanapt, Coartem, Lioresal, Gleevac, Afinitor, Gilenya, Exjade, Tasigna, Voltaren gel, Nexcede (+20 vaccines)	61	29		25	Zelnorm study terminated. Drug withdrawn from market.
Pfizer	52[f]	7	Advil Allergy & Congestion Relief, Advil, Zithromax, Vfend, Revatio, Chantix/ Champix, Geodeon	24	5	2	15	

[a] Source: (FDA, 2013a) FDA. "Postmarket Requirements and Commitments."
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[b] FDA Criteria of delay not met
[c] FDA released GSK from four PMR requirements
[d] FDA released Merck & Co from five PMR requirements
[e] FDA released Novartis from three PMR requirements
[f] FDA released Pfizer from eight PMR requirements (All "released" studies pertained to dosing of phenylephrine in children 2-12 yrs. The drug is no longer labeled for use in children under 12 years and has been removed from OTC drugs for children (Advil Allergy & Congestion Relief, Advil)

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A Case Study of Data Quality: Global Action Networks in Health

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Development in global health is addressed by a complex array of institutions working as "global action networks" (GANs). Network theory suggests a fluidity of connections that is not reflected in most GANs, which are, instead, institutionalized arrangements. We describe the case of a GAN that was ad hoc and temporary. The network successfully produced several now widely used tools for ensuring data quality in systems for monitoring and evaluating programs to reduce the spread of HIV. The ad hoc GAN reflected many of the typical characteristics of GANs, but also exhibited some unique characteristics. Ad hoc GANs focusing on a particular task can be highly adaptive and efficient. We need to learn and foster the circumstances that give rise to them.

INTRODUCTION

The Complex Array of Organizations

Challenges in global health are among the most complex known to humanity. They emerge from interactions between biological ecology, patterns of human behavior, and national and world economics. The interactions of institutions created to address health, particularly in low and middle-income countries, are only slightly less complex.[1] They include global financial collaborations (e.g., the World Bank), global health collaborations (e.g., the Global Fund to Fight AIDS, Tuberculosis and Malaria), national agencies working bilaterally (e.g., United States Agency for International Development [USAID]), national agencies working domestically (e.g., the ministries of health in developing countries), private companies (e.g., Pfizer), foundations (e.g., The Gates Foundation), and other international nonprofit and for profit organizations (e.g., FHI360 and Futures Group).

There are further divisions within many of these institutions. For example, United Nations (UN) programs that address health include the World Health Organization, the Joint UN Program on HIV/AIDS (UNAIDS), the UN Development Program (UNDP), UN Women, the UN Children's Fund (UNICEF), the UN World Food Program (UNWFP), the UN Population Fund (UNFPA), and others. Similarly, bilateral aid will often draw upon the resources of several national institutions. The agencies implementing The U.S. President's Emergency Plan for AIDS Relief (PEPFAR), for example, include the Department of State, USAID, the Department of Defense, the Department of Commerce, the Department of Labor, the Department of Health and Human Services, and the Peace Corps. Furthermore, any one of these agencies may implement its work through contracting mechanisms with other organizations. For example, MEASURE Evaluation is a multi-partner project funded by USAID to enable countries to monitor and evaluate their health programs and to encourage data-

informed policy-making. The lead organization is the University of North Carolina, partnering with Futures Group Global, ICF International, John Snow Incorporated, Management Sciences for Health, and Tulane University.

Governance in Complexity

The array of agencies and organizations listed above can signify a great commitment of financial and human resources to improving global health. But it can also signify competing interests and confusion. There are at least five possible responses within the global health community to this complexity of actors:

- *Inaction.* This can result from inability to get everyone to agree to a plan of action or from doing nothing because of anticipation that agreement will be unachievable. Inaction is often the outcome of either "too many cooks in the kitchen" or is the path of least resistance.
- *Competing answers.* In some instances competition allows better answers to win over lesser ones. But when there is a threat that disregards borders, as with infectious diseases, differences in national goals and programs can translate into ineffective regional or global responses.
- *Taking charge.* The organizations listed above do not relate to each other as if in a global organization chart with a clear hierarchy. Rather, they are part of a network where no organization is formally in charge. Acting autocratically over the others usually results only in resistance.
- *Yielding to a clear answer.* Some innovations and solutions are so clearly helpful and achievable that everyone adopts them without needing to confer with others. The adoption of communication via cell phone systems is an example from the world of information technology. An effective vaccine against HIV would conceivably be met with the same enthusiasm in the world of global health. However, "magic bullets" are not only rare but their implementation is invariably much more complicated than expected, requiring a great deal of international collaboration.
- *Cooperation.* Organizations work cooperatively by sharing their resources and subjugating their internal interests to those of the broader community in order to achieve a broader impact. Cooperation within a complex network is often the only viable option for intentional progress.[2,3,4]

Cooperative arrangements between organizations are usually described in terms of global governance.[5,6] One definition describes them in part as "multi-stakeholder arrangements that aim to fulfill a leadership role in the protection of the global commons or the production of global public goods".[7] There are many terms that aim to define collections of organizations with these objectives, including: global policy networks,[8] global action networks,[9] global issues networks,[10] global health initiatives,[11] a collective impact network,[12] and collective leadership.[13] They address a wide variety of global issues and are typically multi-sectoral (between government, private institutions and civil institutions), but they vary in the degree to which each sector plays a role.[14,15] Buse and Harmer, for example, describe characteristics of one such collaboration model - global public-private health partnerships.[16] Because we are addressing networks of

organizations acting in the arena of global health, we will use the term global action network (GAN) to refer to this constellation of related network concepts.

GANs described in the literature are often named entities. For example, Buse and Harmer's list of 23 global public-private health partnerships includes the Global Alliance for Vaccines and Immunizations; the Global Fund to fight AIDS, TB, and Malaria; the Global Health Council, and Roll Back Malaria.[17]   Descriptions of GAN characteristics are typically derived from observed themes across named GANs. Glasbergen lists five "definitional qualities": global and multi-level organizational structure; utilization of interdisciplinary action-learning and reflective action; consist of stakeholders from several sectors; use of a range of boundary-crossing and diversity-embracing activities to achieve systematic change; and the development of public goods in areas of global sustainability and security.[18] Buse and Harmer also use a similar approach to arrive at seven bad habits of global health partnerships: priorities that are out of sync with the developing countries they aim to benefit; lack of representation with respect to stakeholders; poor governance; vilification of the public sector; inadequate finance; poor harmonization of procedures and practices among the partners; and an overemphasis of loyalty to one's own organization within a partnership.[19]

These named networks have formal structures, such as defined membership and roles.[20,21] However, authors describing GANs appeal to broader networking and complexity theories, emphasizing how network interactions are characterized by adaptability, unpredictability, and an absence of centralized control.[22,23,24] Thus, the relatively formalized nature of named networks may place them on one end of a spectrum defining degrees of formalization. One way to explore and clarify these distinctions is to look for examples of networks acting globally that are not named and do not have the formalized structures of named networks. We present such a case here and, in contrast to the named GANs, we hypothesize that important network interactions in global health are sometimes opportunistic, ad hoc, and temporary. The case we present relates to network interactions to ensure the availability of quality data used to shape health policy.

METHODS

Gathering information on this multi-institutional effort to improve data quality began with an in-person interview with Dr. Sian Curtis, who was the Director of MEASURE Evaluation for the duration of the events described. Dr. Curtis identified the major threads of the story and the principal people involved. The interview was transcribed into a story format and timeline. Subsequent phone interviews and email correspondence with the key actors (David Boone, Win Brown, Karen Hardee, Sara Pacquée-Margolis, and Ronald Tran Ba Huy) added more detail. Additional interviews were conducted with MEASURE Evaluation staff in countries where the tools were applied, and documents describing the in-country processes were also obtained and reviewed.

We reviewed the literature for examples of, and principles for, a network of organizations working at the global level towards a common goal. The search included the terms "network leadership," "leadership within networks," and "organizational network." References in the identified articles and books led to additional sources.

We examined the case study for elements that were consistent with the characteristics of GANs as described in the literature. We also identified elements not captured by those characteristics. We conclude with recommendations for the enhancement of GAN theory and for effective network interactions.

CASE DESCRIPTION

We describe the case in five segments: need, innovation, adaptation, capacity building, and dissemination. The chronology of events is summarized in Table 1.

Need

In the early 2000s, two large funds were created to battle the global epidemic of HIV/AIDS. The Global Fund to Fight AIDS, Tuberculosis and Malaria was created in 2002, following commitments made by countries attending the 2000 G8 Summit in Okinawa, Japan. Initially intended to total 25 billion US dollars in grants over the first five years, the Global Fund paid out just under $20 billion in its first ten years.[25] However, a year after the creation of the Global Fund, US President George Bush committed another $15 billion over five years through the US President's Emergency Plan for AIDS Relief (PEPFAR), which is administered by the Office of the Global AIDS Coordinator (OGAC). Since 2004, PEPFAR has committed more than $30 billion to funding for the AIDS epidemic.[26]

To demonstrate success and ensure continued funding from Congress, OGAC's top priority was to rapidly implement programs and produce results that would demonstrate progress towards reaching its legislatively mandated goals: 2 million people living with HIV on treatment, 7 million new infections averted, and 10 million receiving care and support. In addition, in 2003 WHO set a "3 by 5" target for three million people living with HIV/AIDS in low- and middle-income countries to receive antiretroviral treatment (ART) by the end of 2005.

Program monitoring for these results was complicated by the variety of programs created to achieve them. Some provided resources, such as antiretroviral drugs, directly through local clinics, referred to as direct or downstream services. Other programs provided resources for the development and maintenance of systems, such as health information systems, that did not involve direct patient contact, but were essential for the effective delivery of services. These were referred to as indirect or upstream programs. To achieve the legislatively mandated goals of the program, PEPFAR had to quantify the results of these upstream investments, as well as the downstream support for direct service delivery, by determining the number of people that benefited from HIV specific prevention, care and treatment services. The two streams of reporting made it difficult to ensure that PEPFAR was not double counting those served at the facility level and those reached indirectly through "upstream" investments.

An example of the early difficulties in reporting occurred in Botswana in 2005. The PEPFAR program in Botswana claimed it had supported a number of HIV/AIDS patients receiving antiretroviral therapy (ART) that was the same as the number reported by the Botswana government to WHO. The Government of Botswana challenged the PEPFAR results, claiming that they had in fact yet to receive any PEPFAR funds for HIV treatment. An article describing the challenge was printed on the

front page of the Washington Post.[27] The controversy raised data quality concerns, including the specter of multiple institutions claiming credit for the same outputs and outcomes.

At this time, the Global Fund was also preparing to evaluate the first round of funded programs after two years of implementation (Phase 1) to determine whether to continue funding for another three years (Phase 2). At its first meeting in September 2004, the Technical Evaluation Reference Group (TERG) of the Global Fund discussed the importance of data-verification and quality assurance of data submitted to the Secretariat as the basis for performance-based funding decisions.

The Global Fund, like PEPFAR, was not an implementing entity, but both were funding similar programs, oftentimes in the same countries. To make credible claims that certain outcomes could be attributed to certain inputs, they needed to sort out the effects of their respective efforts. Because they often relied on data collected by national governments with varying degrees of health information infrastructure, both wanted to ensure that the data were of good quality. The Global Fund TERG and PEPFAR's Office of Strategic Information were charged with evaluation of their respective programs, and they both identified the need for an instrument to assess the quality of routinely reported data and identify where improvements were necessary. When it learned that the USAID component of PEPFAR was working on the issues through MEASURE Evaluation, the Global Fund decided to also work through MEASURE Evaluation to develop the data quality tools it needed, and provided additional funding for the effort.

In 2005, MEASURE Evaluation was in its second five-year period of funding. Although the Project had no authority to impose standards on other institutions such as the Global Fund, it was mandated to work closely with them. Collaboration with and through MEASURE Evaluation was a logical means of devising an instrument that met the needs of all stakeholders because of its international experience with health information systems and its collaborative nature. In August 2005, representatives from the Global Fund, PEPFAR and MEASURE Evaluation met in Washington, DC to develop a shared agenda for a data quality assurance framework and associated instruments.

Innovation

The Global Fund envisioned two companion tools: one to assess the monitoring and evaluation (M&E) systems in place for data collection and the other to assess the data quality reported by programs. A third was eventually developed (described below, under Adaptation), and a fourth was already under development by MEASURE Evaluation when the collaboration started: the Data Quality Assurance Tool for [PEPFAR] Program Level Indicators.[28]

A number of existing tools or approaches served as sources of inspiration for, or as components of the data quality tools eventually developed. They included: (1) the Global Alliance for Vaccines and Immunization (GAVI) data quality tool (Global Alliance for Vaccines and Immunization, online); [29](2) the 2004 Global Fund Monitoring and Evaluation Toolkit (not available online); (3) the PEPFAR Indicators Reference Guide for FY 2006 Reporting and FY 2007 Planning (not available online); (4) the 1998 USAID Performance Monitoring and Evaluation TIPS brief #12, entitled "Guidelines for Indicator and Data Quality";[30] and (5) a data quality assessment tool developed by Khulisa Management Services of South Africa (not available online).

The MEASURE Evaluation tool development team consisted of Win Brown and Karen Hardee of the Futures Group and David Boone of JSI. They were joined by Ron Stouffer, a retired auditor from the US General Accounting Office, and Ronald Tran Ba Huy, of the Strategic Information and Evaluation Unit of the Global Fund, was also instrumental in the development of the tools. A number of others contributed in important ways, including Sara Pacquée-Margolis and Annie Latour of OGAC; Philip Setel, then of MEASURE Evaluation, Sonya Schmidt of Futures Group and Cyril Pervilhac of WHO.

The first tool developed, eventually called the Monitoring and Evaluation Systems Strengthening Tool (MESST) was drafted in 2005.[31] Its principal purpose was to verify that recipients of Global Fund grants had the capacity to report reliable results to the Fund. The MESST was not specific to any particular disease or health outcome. It consisted of a checklist to assess a country's monitoring and evaluation systems and data management capacities. The tool included guidance for developing plans to correct identified weaknesses.

Development of the Data Quality Audit (DQA) began in parallel with the MESST.[32] Its purpose was to ensure the accuracy of data reported by programs and used by donors for making performance-based funding decisions. The tool focused on data related to the Global Fund's "Top Ten" indicators for routine Global Fund reporting. These "Top Ten" AIDS-related indicators were also reported to PEPFAR.

Adaptation

MESST was first pilot tested in Rwanda in 2005. In meetings with Rwanda's Ministry of Health, the tool development team gained a better understanding of the country's information system and data flow. To make the tool more accessible to them, they developed a "dashboard," consisting of a spreadsheet programed to identify priorities and areas requiring action. Testing in other countries confirmed that the tool asked the right questions and provided useful and accessible information.

The DQA tool was first pilot tested in Tanzania in late 2006. In this instance, the team found that only minor adjustments were needed. The second implementation in Vietnam a few months later confirmed that the tool was ready for broader use.

Before implementing them widely, the development team – with representatives from MEASURE Evaluation and the Global Fund - wanted to be sure the tools met the needs of the original stakeholders, and that the stakeholders had an opportunity for input before the tools were finalized. In February 2007, the Global Fund hosted a gathering of representatives from WHO, UNAIDS, Stop TB, Roll Back Malaria, the World Bank, and the Health Metrics Network for a two-day workshop on the tools at the WHO offices in Geneva. In addition to refining the tools, the organizations confirmed their utility for their respective programs.

Participants in the Geneva meeting endorsed the idea proposed by MEASURE Evaluation of a simplified version of the DQA that would not just audit data quality, but help countries and implementers prepare for external audits and build their capacity to create and maintain an information system that would continuously generate and use high quality data. Once developed, it was called the routine data quality assessment (RDQA).[33]

Building capacity

Having developed a set of tools, pilot tested them and adjusted them to country needs and the recommendations of the international health community, the next step was to build the capacity of organizations and countries to use them. This step consisted of publishing the tools, developing training materials, training trainers, conducting workshops, and working alongside those implementing the tools.

The tools and guidelines for using them were posted on the MEASURE Evaluation and Global Fund websites, and were immediately in demand by international health donors, implementing partners, USAID in-country missions, and country governments. Guidelines most highly demanded were for programs using tools for data pertaining to prevention of mother-to-child transmission (PMTCT) of HIV, the administration of anti-retroviral therapy (ART), and tuberculosis case detection and treatment.

To build capacity for training in tool implementation, the developers presented the tools at PEPFAR regional meetings in 2006 and led a series of workshops among MEASURE Evaluation staff, thereby creating a team of trainers. In 2007, they trained the HIV Monitoring and Evaluation Resource Group (MERG), with representatives from UNAIDS, the Global Fund, and the PEPFAR agencies; and in the subsequent year, they led a workshop for the partners selected by the Global Fund to implement DQAs. In 2007, MEASURE Evaluation staff members, who were often host country nationals, conducted the first training of Ministry of Health, Global Fund, and PEPFAR implementing partners in Nigeria. Since then, through 2011, 22 more trainings were conducted in 20 countries.

The best capacity building occurred when a tool was implemented in collaboration with national M&E staff. This was first done in Tanzania, where the USAID mission asked MEASURE Evaluation to conduct a DQA. Other collaborative implementations soon followed in Kenya, South Africa, Lesotho and Swaziland.

Dissemination

Dissemination of any tool or approach entails widespread application and adoption by ministries of health and contracting agents. In the case of data quality tools, widespread use was aided when the Global Fund began requiring in 2005 that organizations seeking grants conduct an assessment of M&E systems in order to identify gaps and strengthen measures. As recommended by UNAIDS, they asked programs to invest 5-10% of their budgets in M&E. (The requirement for this level of M&E investment was not enforced and was seldom achieved.) When it became available, the MESST was the tool most recognized for this purpose and was thus the tool most often used.

The Global Fund's local fund agents (LFAs) also have a mandate to monitor the quality of services and related information for programs financed by the Fund. Before the availability of the data quality tools, they used non-standardized methods to assess data quality. In 2009, the Global Fund began standardizing the process through use of the DQA. From 2008 through 2011, the Global Fund conducted DQAs in 55 countries.

Botswana, Rwanda, Nigeria, Cote d'Ivoire, and South Africa have demonstrated signs of adopting the tools, integrating them into their health information systems.

Rwanda, for example, financed its routine data quality assessment in part from the Ministry of Health (MOH). Upon request from the Ministry, a country team composed of representatives from the national-level health management information systems staff was trained by MEASURE Evaluation to conduct data quality audits. MEASURE Evaluation was then asked to train the national level team how to train others ("training of trainers") to enable the implementation of data quality audits by MOH staff at the sub-national level. Moreover, apart from the need to report to PEPFAR, the Rwanda MOH used the RDQA tool to integrate M&E strengthening into the national strategic plan.

Interest in the data quality tools continues. Since July 2, 2008, when a Data Quality Assurance web page was created on the MEASURE Evaluation website, there have been over 16,000 downloads of the MESST tool, over 10,000 downloads of the DQA tool. The RDQA tool is in a format that does not allow for counting downloads. The tools have also been disseminated from the websites of other organizations, such as the Global Fund. Counts of downloads from non-MEASURE Evaluation sites are not available.

DISCUSSION

The evolution of the data quality tools occurred in the context of a network of multi-lateral and bilateral organizations, NGOs, and governmental agencies. We consider here how elements of this network are consistent with the characteristics of GANs described in the literature, how they could have achieved those characteristics more fully, and illustrate characteristics they exhibited that are not described in the literature.

Democracy

A network is not a hierarchy that is managed through command and control.[34,35,36] Many agencies and organizations operating in the realm of global health are accustomed to being the most powerful in their environment, setting agendas and making final decisions. Even so, each has a limited reach and none can issue an edict that will be carried out globally and faithfully by all other stakeholders. For a tool or an approach to be used globally, each stakeholder needs to have a voice in the development process, and to be free from top-down coercion.[37,38] Moreover, in complex issues, new perspectives and approaches championed by new leaders are often needed. Collaboration networks allow for the emergence of new ideas and new leaders.[39,40]

In the story of the data quality tools, there were two large organizations in particular that initiated the tool development: PEPFAR and the Global Fund. Either one could have developed the tools themselves and required that their grantees use them. However, they could not guarantee buy-in by other organizations, nor prevent the creation of competing tools. To achieve global use and thus a common language and comparable measures across countries, they each had to yield a bit of their power to a more democratic process. The process was steered by two projects with a mandate for global collaboration: MEASURE Evaluation, representing PEPFAR, and the Global Fund. Glimpses of this democratic approach were observed when several organizations gathered in Washington DC and Geneva in August 2005 to determine needs and roles, and then in Geneva in October 2007 to review the proposed tools.

The democratic process was weaker than it could have been, however, had it not been dominated by two very large, powerful and well-funded organizations. Although PEPFAR and the Global Fund used their influence in part to seek input from others, the final decisions were largely theirs.

Diversity

Innovation is most likely to occur when people or organizations with different experiences share their perspectives with each other.[41] It is least likely to happen in situations of "group think," where all group members have had similar experiences or hold the same perspective. In addition, the networking of diverse organizations can break down silos and unify sectors that seldom interact.[42] The diversity of organizations involved in developing the data quality tools included multi-lateral and bilateral organizations, NGOs, universities, and ministries of health. Diversity was also a part of MEASURE Evaluation, which is a partnership between two universities, three companies, an NGO, and the US government. Each network actor contributed a different but complementary perspective on ways to enhance the quality of data to be used for guiding global, national and local health policies and program. In addition, each played a different but complementary role: PEPFAR and the Global Fund provided funding for various activities, MEASURE Evaluation and the Global Fund created the tool, individual host country governments facilitated the first applications and adaptations of the tools, and the Global Fund facilitated the use of the tools through its grant requirements. Each of these roles was unique, and without any one of them, the tools would not have achieved widespread use.

However, the network would have been more diverse if countries where the tools were to be applied had been included in more decision-making discussions. For example, low and middle-income countries were underrepresented in the stakeholder meetings in Geneva.

Trust

The key element that enables a democratic network of diverse organizations to work together is trust.[43,44,45,46] Two factors that engendered trust among the international organizations in the present instance were competence and communication. The number of people working in global health is finite, and over the duration of a career, they tend to work in several of the agencies and organizations listed above. They come to know each other by working together in the same organization or on multi-organizational projects. They can gain a good reputation among their peers by showing themselves to hold high standards, to be productive, and to work well with others. The development of data quality tools included a number of veterans in global health who were trusted by others on both personal and professional levels. And those who developed the tools, veterans and newcomers alike, communicated frequently among themselves and with other stakeholders through email, phone calls, and meetings, keeping the process transparent.

Although trust among stakeholders was prominent in the development of the data quality tools, it wasn't ubiquitous. There was at least one other data quality

initiative outside of the network described here that led to a sense of competition between the respective efforts rather than cooperation.

A global public good

A third element of trust is worth singling out: a non-proprietary product. That is, none of the stakeholders intends to claim the product as their own and the contributions of many are acknowledged. In his description of global action networks, Waddell calls this a "global public good," or a product that is available to all, and use by one party doesn't reduce its availability to others.[47] These qualities stand in contrast to the idea of intellectual property, in which an idea or a product is carefully guarded to produce an academic reputation or a market profit. Not only were the data quality tools posted online without a copyright, but there was also considerable effort and expense put into training others in their use.

Although the products are not proprietary, they are also not free of ownership claims. Each organization that contributed funds to the product required that its logo be placed on the cover. This degree of labeling can be contrasted with wiki or open-source processes in which virtually anyone can contribute to a product and contributions remain largely anonymous.

Secretariat

Even with a strong foundation of trust, collective action networks function best with an organization that serves as a secretariat or coordinator.[48,49,50] To engender the trust of all network members, it often works best if the secretariat is not one of the original network members, but is created to serve the network. MEASURE Evaluation's cooperative agreement with USAID allowed it to both serve as the M&E arm of USAID, and to serve in some cases as a secretariat among the many actors in global health.

MEASURE Evaluation, however, did not act alone in the secretariat role. The Global Fund also initiated meetings and actions. To achieve a common goal recognized and valued by all stakeholders, MEASURE Evaluation and the Global Fund had to work closely together.

A common agenda

A collective action network directs its energies toward a shared goal.[51,52,53,54] The need for data quality was fundamental to virtually every other goal of the stakeholders. Without reliable data, there could be no systematic method of allocating resources or evaluating policies and programs. The network made the agenda even more common by adapting the tools for conditions other than HIV/AIDS, such as malaria and TB.

A common agenda can be dictated from above or it can emerge from the grassroots. The need for data quality tools was driven largely by a desire for accountability for funds spent by two large organizations. If they also discerned the need for data quality through input from other organizations in global health, the agenda of improving data quality was commonly held among the stakeholders. If, on the other hand, the agenda was imposed out of the organizations' self-interest and by virtue of their size and influence, it may not have been equally valued by all stakeholders.

Adequate funding

Creation of a global public good requires funding over an extended period of time.[55],[56] Each step in this story – innovation, adaptation, capacity building, and dissemination – required personnel, travel, communications, and more. In addition to the work done by individuals named, each of the stakeholders sent representatives to meetings and country personnel committed time to the application of the tools. USAID's contributions through MEASURE Evaluation cost an estimated $1,235,000 from 2005 through 2011, spanning two five-year funding cycles. Thus, the funding was not only sizable, but over an extended period. Network initiatives seldom achieve their objectives within a predefined time frame or a single 5-year funding cycle.

NEW INSIGHTS

The network of actors that created and disseminated the data quality tools included two that were themselves networks. The Global Fund is one of the named GANs mentioned in our introduction.[57] As also described above, MEASURE Evaluation is an affiliation of universities, companies, a civil society organization, and the US government that works in concert with host governments, and often relies on agreements and contracts with still other organizations to achieve its ends. This case may represent, then, a network of networks. At present, though, the network described no longer has a shared goal. The actors continue with their respective missions, but with the data quality products produced and disseminated, they are no longer focusing on that common goal.

This network emerged to meet a shared need, and then dissolved once the need was met. It existed long enough to achieve the goal but not long enough to formalize the network's relations or take on a name. Waddell might call this a "task network." He proposed a network typology based on three scales: levels of knowledge, types of change, and stakeholder diversity.[58] According to his model, a global action network is the one operating in the highest degree of each of these while a task network addresses lower levels of each scale. However, as we have noted, the data quality network demonstrated many of the characteristics of what he considers to be GANs. More basically, their action was global and the way they emerged and functioned was consistent with network theory.

Alternatively, Waddell might call this a partnership, formed by a subset of network members for a particular time-limited task.[59] However, this group did not form from within an existing, named network.

In their description of five types of collaboration, Kania and Kramer include "social sector networks," which they characterize as *ad hoc*, short-term, and focused principally on information sharing.[60] In our example, the group was *ad hoc* and short-term, but focused on developing a shared measurement system, and having mutually reinforcing activities; two characteristics of what Kania and Kramer call a collective impact initiative, and what we are calling a global action network.

We suggest, then, that there is a spectrum of degrees of formalization between actors in a GAN. On the less formalized end of the spectrum, there are actions that are opportunistic, *ad hoc* and temporary. Functioning this way may provide adaptability and responsiveness unachievable by more formalized network arrangements. Moreover,

they can be realized without sacrificing democracy, diversity, accountability and other characteristics of GANs.

Ad hoc GANs are consistent with USAID's emphasis on collaboration. For example, the recent request for applications for Phase IV of MEASURE Evaluation states "The recipient is expected to collaborate effectively with a wide variety of global development partners."[61] Examples they list include other US government agencies, host country governments, multilateral organizations, private sector entities, and NGOs. A means of mapping collaborations, developed by the USAID mission in Rwanda, is provided on the website of the USAID Learning Lab.[62]

The significant roles of both the Global Fund and MEASURE Evaluation suggest that the network case we describe did not have a single secretariat. Although this stands in contrast to the descriptions of global action networks, it is consistent with network theory in which there are often multiple centers of activity.[63] Achieving progress toward a common goal requires close communication and coordination between various centers of activity. But if that is achieved, the multiple centers can tap into their respective networks, bring additional resources, and provide adaptability in obtaining the common good sought.

The close communication required was realized in the present case by a number of individuals representing the institutions in the network who coalesced into a team. They did so by exhibiting the technical and interpersonal skills that engender trust. In this instance, we see the network functioning at two levels: the institution and the individual. Neither could have realized the common goal without the other. The individuals needed the authority and reach of the institutions, and the institutions needed a select group of individuals to work together efficiently. As with the other new insights described, we see with the individual-level relations an ability for a select group of individuals to transcend some institutional bureaucratic processes, bringing more flexibility and efficiency.

A tool such as the DQA, once successfully disseminated and applied, benefits many countries, donors and organizations over an extended period of time. In such situations, it is difficult, if not impossible, to link the global benefits accrued to the particular roles played by those who contributed to tool creation and implementation. A donor's desire for direct attribution may cause it to refrain from participation in such a network action, and thereby threaten the availability of funds for these critical collaborations. Ironically, then, what began as an attempt to disentangle funding and benefits by major donors led to a collaborative process and product that defies direct attribution. However, the product that emerged provided benefit to each of the donors well beyond what they could have achieved had they acted on their own.

RECOMMENDATIONS

In the case described, we have identified a number of characteristics that are not prominent in the literature on global action networks. If they are not exclusive to this case, the characteristics offer opportunities for gains in flexibility and efficiency without sacrificing the characteristics valued in more formal networks. The degree to which the characteristics are more common can be determined with analysis of additional case studies of *ad hoc* networks similar to the one described. In particular, we suggest the systematic study of relationships between individuals representing the institutions in a

network. We suspect that the success of an *ad hoc* network effort is heavily dependent on the relations between the individual representatives. The more the elements of those relationships are understood, the better the chances of selecting and equipping individuals to play the inter-institutional roles, and the greater the chances of the network effort succeeding.

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Table 1: Chronology of milestones in the development and use of global health data quality tools

Date	Activity
September 2004	Technical Evaluation Reference Group (TERG) of the Global Fund recommends development of data-verification and quality assurance mechanisms as a basis for performance-based funding decisions.

June 2005	OGAC Strategic Information team requested MEASURE Evaluation to visit Kenya, Zambia, and South Africa to gather info on data collection/quality assurance procedures in place.
August 2005	Meeting in Washington, DC, with representatives from PEPFAR, Global Fund, and MEASURE Evaluation to develop a common agenda around a data quality assurance framework for global HIV/AIDS programs.
August 2005	Follow-up meetings in Geneva, Switzerland, to further discuss MESST.
September 2005	Data quality harmonization presentation given to the Global Fund TERG.
September 2005	1st pilot test of MESST in Rwanda.
November 2005	Meeting in Geneva to clarify roles among Health Metrics Network, Global Fund, and MEASURE Evaluation for completing the data quality tools.
December 2005– February 2006	2nd wave of pilot tests of MESST in Russia, Niger, Congo, Chile, Bangladesh and China.
November 2006	1st pilot test of the DQA tool in Dar es Salaam, Tanzania
June- July 2006	PEPFAR regional workshops where the tools were introduced: Port-of-Spain, Trinidad; Dakar, Senegal; Bangkok, Thailand
February 2007	Multi-stakeholder workshop in Geneva at WHO to refine DQA tool with Global Fund, PEPFAR, USAID, WHO, UNAIDS, Stop TB, Roll Back Malaria, HMN and MEASURE Evaluation.
July–October 2007	2nd wave of DQA pilot tests in Rwanda, Vietnam and Madagascar.
July-August 2007	Workshop in Washington, DC, and then later in Johannesburg, South Africa on data quality assurance tools framework.
October 2007	RDQA workshop for UNAIDS, WHO, Health Metrics Network, PEPFAR, Global Fund, World Bank, and Roll Back Malaria.
November 2007	Presentation to HIV MERG on DQA and RDQA tools.

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International Responses to Sexual Violence in Situations of Armed Conflict

Jane Galvão, PhD

INTRODUCTION

This commentary describes efforts to address sexual violence, especially in situations of armed conflict, and bringing attention to this issue in connection with the Post-2015 United Nations (UN) Development Agenda.[1] Analysis on sexual violence during armed conflict is not a new subject and even an initiative UN Action against Sexual Violence in Conflict (UN Action) was launched in March 2007, bringing together 13 UN entities,[2] but here I will focus on some of the international responses, and particularly on the UN Security Council resolutions. I will highlight the resolutions adopted by the UN Security Council from the year 2000 to 2011, illustrate the issue mentioning Kosovo and Rwanda as examples of prosecution of perpetrators of sexual violence during armed conflicts, as well as the United Kingdom *Preventing Sexual Violence in Conflict Initiative*, launched in 2012.[3]

THE INVOLVEMENT OF THE UNITED NATIONS SECURITY COUNCIL

Under the UN Charter, all Member States are obligated to comply with Council decisions, and this gives them particular weight, increasing their potential influence as national governments develop and implement national policies, establish guidelines, and undertake new initiatives. The Council has five permanent Members — China, France, the Russian Federation, the United Kingdom, and the United States — and 10 non-permanent Members elected for two-year terms by the UN General Assembly.

The UK *Preventing Sexual Violence in Conflict Initiative*, which will be addressed in some detail below, offers an example of this potential; its text makes explicit reference to a Security Council resolution adopted in the year 2000.[4]

When considering the resolutions described below, it is important to have in mind that the Council's interest in children and armed conflict, and women, peace and security, gained particular force after 1999 (Resolution 1261)[5] and the year 2000 (Resolution 1325).[6] The greater part of the resolutions included here, accordingly, fall under these two concerns.

There are two points regarding the language of these resolutions that should be noted: the first is that at times, in the "women and peace and security" resolutions, girls are also mentioned. The second is that in the "children and armed conflict" resolutions, boys and girls are at times mentioned, but in general the reference is to children. Since the resolutions are not always clear regarding gender, I variously refer to sexual violence, sexual violence against women and girls, and sometimes, sexual violence against children. What needs to be emphasized, however, is that boys and men also suffer sexual violence, including rape. Some authors mention that sexual violence against men and boys in armed conflict is not yet fully addressed and it is one of the most well-kept "secrets of war."[7,8,9,10]

Resolutions Adopted by the UN Security Council: 2000 to 2011

Since the year 2000, the UN Security Council has adopted several resolutions dealing with sexual violence in the context of armed conflicts; I highlight below seven of these to illustrate how the resolutions express, reaffirm or recognize this issue.

- Resolution 1325, adopted in October 2000.[11] While this resolution addresses peace and security broadly, it includes at least two clauses on violence in the context of armed conflicts emphasizing "the responsibility of all states to put an end to impunity and to prosecute those responsible for genocide, crimes against humanity, and war crimes including those relating to sexual and other violence against women and girls and in this regard *stresses* to exclude these crimes from amnesty, where feasible, from amnesty provisions."
- Resolution 1820, adopted in June 2008.[12] Violence against women and girls is clearly stated in this resolution, and almost all clauses are related to this issue.
- Resolution 1882, adopted in August 2009.[13] This resolution deals more specifically with the situation of children in armed conflict and addresses sexual violence against children, expressing deep concerns "about the high incidence and appalling levels of brutality of rape and other forms of sexual violence committed against children, in the context of and associated with armed conflict including the use or commissioning of rape and other forms of sexual violence in some situations as a tactic of war."
- Resolution 1888, adopted in September 2009.[14] This resolution deals in its totality with sexual violence against women and girls in situations of armed conflict.
- Resolution 1889, adopted in October 2009.[15] This resolution principally concerns peacekeeping operations, yet emphasizes the responsibility of all states to put an end to impunity and to prosecute those responsible for all forms of violence committed against women and girls in armed conflicts, including rape and other sexual violence.
- Resolution 1960, adopted in December 2010.[16] This resolution recalls previous ones and calls for greater collaboration and coordination among agencies and countries to better address the subject of violence against women and girls.
- Resolution 1983, adopted in June 2011.[17] This resolution makes an explicit link between sexual violence and HIV/AIDS, recognizing "that conditions of violence and instability in conflict and post-conflict situations can exacerbate the HIV epidemic." Regarding the resolution, UN Secretary-General Ban Ki-moon commented that the resolution recognizes "that rape was still a weapon of choice in many conflicts".[18]

RAPE AND OTHER FORMS OF SEXUAL VIOLENCE IN SITUATIONS OF ARMED CONFLICT

The occurrence of sexual violence especially during and after armed conflict, has been extensively documented.[19,20,21,22,23,24,25] In recent years, as mentioned below, International Criminal Tribunals were able to prosecute and condemn some perpetrators of sexual violence during armed conflict.[26]

Another dimension of this issue is the categorization of rape as a "weapon"[27] to describe the unspeakable reality faced by women, men, girls and boys during and after

armed conflict. Country analyses, particularly those published by Human Rights Watch (HRW), have documented sexual violence perpetrated during and after armed conflicts and have provided details accounts of the use of rape "as weapon of war" in the Democratic Republic of the Congo (DRC), Eastern Congo, Kosovo, Rwanda, and Sierra Leone. [28,29,30,31,32,33]

During the 1990s, two countries — Rwanda and Kosovo — led to landmark cases where some perpetrators of rape and other forms of sexual violence during their corresponding armed conflicts were prosecuted and convicted; in both cases, rape and other forms of sexual violence were considered as crimes against humanity and war crimes.[34] In 1993, the UN Security Council created the International Criminal Tribunal for the former Yugoslavia (ICTY), and in 1994, the International Criminal Tribunal for Rwanda (ICTR).

Kosovo

In Kosovo, in 1999, according to HRW, rapes "were not rare and isolated acts committed by individual Serbian or Yugoslav forces, but rather were used deliberately as an instrument to terrorize the civilian population, extort money from families, and push people to flee their homes".[30]

The ICTY, established in May 1993, but which grew to include the Kosovo crimes and as stated in the website "those indicted by the ICTY include heads of state, prime ministers, army chiefs-of-staff, interior ministers and many other high- and mid-level political, military and police leaders from various parties to the Yugoslav conflicts. Its indictments address crimes committed from 1991 to 2001 against members of various ethnic groups in Croatia, Bosnia and Herzegovina, Serbia, Kosovo and the Former Yugoslav Republic of Macedonia."

In February 2001, the ICTY convicted three soldiers for rape as a crime against humanity, and found that rape was used as an instrument of terror; the sentences applied were between 28 and 12 years for rape, torture, and enslavement. [35]

Rwanda

During the genocide in Rwanda in 1994, according to reports, HIV positive men were instructed to rape women, and, some add, with the specific intention of infecting them with HIV;[36] the same allegation has been made for the DRC.[37]

Rwanda offers a rare example where a civil servant has been prosecuted and convicted for rape among other acts classified as war crimes and crimes against humanity. In June 2011, the ICTR found Pauline Nyiramasuhuko, "Rwanda's former minister for family and women's affairs, guilty of genocide, war crimes and crimes against humanity, including rape, for her role in planning and ordering others to carry out these crimes;[38] she was sentenced to life imprisonment.

THE UNITED KINGDOM INITIATIVE

The UK *Preventing Sexual Violence in Conflict Initiative*, launched in May 2012,[3] is described as aiming "to replace the culture of impunity with one of deterrence — by increasing the number of perpetrators brought to justice both internationally and

nationally; by strengthening international efforts and co-ordination to prevent and respond to sexual violence; and by supporting states build national capacity." 3

The UK has asserted that it will contribute to these aims by: "launching a sustained campaign through the UK's Presidency of the G8 in 2013 to build a global partnership to prevent sexual violence in conflict [...]". Similarly, the UK declared its intention to increase its funding to the UN Secretary-General Special Representative on Sexual Violence in Conflict to support their efforts to strengthen national capacity to investigative, prosecute perpetrators of sexual violence and to protect survivors and witnesses.[3]

Development in this regard is encouraging, and suggests that the UK is keeping its promise: during the G8 Foreign Ministers meeting in April 2013, the Ministers endorsed the *Declaration on Preventing Sexual Violence in Conflict*.[39]

FINAL REMARKS

As mentioned above, the prosecution and conviction of individuals accused of rape and other forms of sexual violence in armed conflict has shown that these trials, despite real challenges, can be pursued effectively, and equally fundamental is the support for the individuals who suffered such acts of violence. But it is also important to recognize that just a fraction of the perpetrators of these acts are brought to justice and much more should be done to address this situation.[40]

The 2012 *Millennium Development Goals Report* remarked that, in 2011, armed conflict had uprooted more than 4 million people, noting that this was "the highest number in many years" and that "at the end of 2011, an estimated 42.5 million people worldwide were living in a place to which they had been forcibly displaced due to conflict or persecution. [41] These numbers offer a glimpse of the violence faced by civilians during and after situations of armed conflict, and more especially the potential number of individuals (women, men, girls and boys) who could suffer sexual violence. The figures likewise highlight the expansion of armed conflicts, globally, and the chronic state of conflict faced by many countries and regions of the world. These complex scenarios will require a broadening of our understanding and a diversity of concrete measures, if the tide of sexual violence during and after armed conflict is to be turned.

Since 2011-2012, several important developments happened, including high-level forums, such as the 57th Commission on the Status of Women (CSW, March 2013) where the theme was *Elimination and Prevention of all Forms of Violence against Women and Girls*.[42] An event in May 2013 led to the pledge by the Attorneys General of Australia, Canada, England and Wales, New Zealand, and the United States to support prosecutions of rape and sexual violence in war;[43] and in June 2013, the UN Security Council adopted a resolution solely dedicated to sexual violence in armed conflict.[44] It is also worth mentioning the publication in January 2014 of the *Prosecution of Sexual Violence*, a best practices manual for the prosecution of sexual violence crimes in post-conflict regions.[45]

The discussions around the Post-2015 UN Development Agenda offers an opportunity to address sexual violence in armed conflict within a broader perspective, including strengthening the synergies with the diverse range of organizations that are implementing projects, programs, and policies in the field of sexual violence. Though much remains to be done, the following years could bring true advances against these

urgent threats to the life, health and well-being faced by women, girls, men, and boys across the globe.

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Disclaimer: Jane Galvão is a staff member of UNITAID/World Health Organization (WHO). The author alone is responsible for the views expressed in this publication and they do not necessarily represent the decisions or policies of UNITAID/WHO.

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The Evolving Field of Global Health Education

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As the field of global health grows, the network of stakeholders and the influences on program development become more complex. Future leaders need to be prepared with skills to navigate and negotiate within the increasing global health governance structures. Leaders in education have called for new techniques to engage students through active and experiential learning. Simulation education, which has been used in fields such as political science and policy making, is perfectly suited to meet educators' needs in teaching global health governance, program development and response. This article describes the creation of a global health related simulation and a discussion of the framework from which it was developed and implemented. This could be used as a template to develop other global health related simulations.

INTRODUCTION

As the world effectively shrinks, health epidemics such as HIV/AIDs and food shortages increasingly become issues that can travel quickly across borders and affect international populations. These phenomena require a collective response from interdisciplinary stakeholders. Consequently, global health governance structures have rapidly expanded from the World Health Organization (WHO), which initially focused on cure and eradication of single diseases, to a wide range of stakeholders that handle systems, politics, and social equity in global health policy making and implementation.[1] As the number of actors grows to include academic institutions, branches of the military and local governments, leaders in the field call for robust responses to coordinate efforts in distribution of public services and goods.[2]

Accordingly, education for emerging leaders must evolve. Student interest in global health has led to an unprecedented expansion and evolution of university-based education opportunities, as institutions have been pushed to develop numerous formal global health training programs.[3] The field has developed a list of competencies required for the next generation of effective global health professionals.[4] Educators have determined that students of global health must master complex interdisciplinary concepts and apply this knowledge in key leadership and policy-making positions.[5,6] To develop these skills, the Associated Schools of Public Health (ASPH) and the Consortium of Universities for Global Health (CUGH) have called for innovative training mechanisms in which students are actively engaged in problem-solving and skills development.[7]

SIMULATIONS AS EDUCATIONAL STRATEGIES

Simulation exercises are used in other fields to engage students in active learning exercises to develop practical skills and knowledge.[8] Model United Nations, one of the oldest simulation models, has been shown to sharpen students' appreciation of complex motivations and negotiations of stakeholders.[9] Other exercises simulating the European

Union, US Foreign Policy Creation, and Mock Trial have been shown to develop depth of knowledge and negotiation skills.[10,11,12]   Active learning through simulation has also been shown to improve long-term knowledge retention, negotiation skills, insight into organizational process development of critical thinking skills, and presentation skills.[13] Simulations have also been used in global health education; University of Montreal hosts a Model WHO and University of California, San Francisco hosts a yearly simulation exercise features a response to a complex humanitarian emergencies.

    We used a simulation model to create an experiential educational opportunity in which students would learn about processes in global health governance by participating in a mock international policy meeting. This simulation was inspired by the annual University of Montreal Model WHO conference, and was expanded to include interdisciplinary and multinational players such as the World Bank, bilateral aid organizations, and think tanks, in order to recreate the unique interests and tensions that arise in international policy development.[14]

SIMULATION DEVELOPMENT AND IMPLEMENTATION

Case Development

    The simulation focused on food security, a topic that integrates issues related to health, environment, economics, development, agriculture, and trade. This provided the ideal backdrop in which international actors with diverse priorities but a shared interest in food security have to work together to develop a common action plan. The conflict that might arise between an organization that prioritizes health and safety and an organization interested in economic development would provide an example through which students could understand differing motivations, conflict resolution and negotiation.

Simulation Premise

"In 2015, a major drought swept across Sub-Saharan Africa, which, when exacerbated by increasing food prices, resulted in the worst famine thus far in the 21st Century. Despite a global relief effort headed by the World Food Program, The World Health Organization estimates that millions of people died across sub-Saharan Africa due to direct and indirect effects of the famine, with many succumbing to hunger but most deaths related to a perfect storm of malnutrition, infectious disease, lack of access to safe water, and exacerbation of simmering conflicts. Urban areas suffered greatly during the famine. The city of Kampala, Uganda, however, was relatively unscathed, in part due to a progressive policy of urban farming that began almost 10 years earlier. In January 2016, the African Union calls a summit to draft a Famine Prevention Plan in the hopes that some of the lessons learned in Kampala can be expanded to more settings across all of Africa."

Educational Objectives

The primary educational goal of the simulation was for students to apply theoretical knowledge to a practical simulation. The simulation creators developed specific and measurable goals that incorporated elements of theory and practical skills.

Specific Objectives

1. Describe the balance that exists between growing more food, environmental degradation, and climate change.
2. Describe aspects of successful and efficient agriculture including, but not limited to, better crop diversity, integrated agro-forestry systems, aquaculture and small livestock ventures, education and social marketing strategies that strengthen local food systems and promotion of cultivation and consumption of local micronutrient rich foods.
3. Generate a working list of the barriers to robust agriculture and their relative importance. Things to consider are infrastructure, well implemented government aid, fertilizer quality, market forces, gender and social dynamics
4. Describe the mechanisms for how food insecurity can contribute to antiretroviral (ARV) non-adherence, treatment interruptions, or postponement of ARV initiation.
5. Describe the importance of global food prices, external imports and domestic food production in tackling food security issues

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Participants

Forty-two interdisciplinary trainees were recruited through national and local list-serves including the Global Health Education Consortium, the American Medical Students Association, the Bay Area International Health Group, the American Public Health Association, and the Student Lancet. The cohort consisted of 30 medical students (including 3 MD/MPH students, 1 MD/JD student, 1 masters in global health student, and a 4:1 ratio of MS1-2 to MS3-4's), 6 undergraduates (25%), 1 MPH/PhD student, 1 student with a masters in urban planning, and 1 masters in global health student. Two students were immigrants to the United States (from Jordan and Mexico). Prior experience in global health varied greatly. Over 50% had international global health experience (Peace Corps, international research scholarships, international volunteer work). Over forty percent held leadership positions in local and national student-run organizations with a global health focus (AMSA, NMSA, and other campus organizations). We assigned these participants to one of 12 roles.

Assignments and Preparation

Students were introduced to the simulation with a description of the problem and were told that they would be charged with creating a Famine Prevention Plan (FPP) during a global policy conference. They would draw from the lessons of one successful

community project, from Kampala, Uganda to develop a larger policy initiative for the greater East African region.

The simulation was set into a one-weekend conference for participants who traveled to UC San Francisco from across the United States. One month before the simulation, we provided each participant with background information specific to their assigned group to guide their thinking.   This background information included organization-unique factors and information on food security and Kampala urban agriculture initiatives. We required participants to submit position papers prior to arrival to ensure individually focused research. Team members were invited to interact with each other to discuss their position papers. The organizers compiled these various essays to distribute as a PDF file to the students at the end of the exercise for reference and to complement the participatory aspects of the active simulation.

Process and Negotiation

The simulation exercise involved three phases in which students were tasked to create a Famine Prevention Plan. The phases were spread throughout an entire weekend with interspersed lectures, topic presentations, and small group discussions to foster informal idea sharing, reflection, and prepare for the upcoming phases. Each phase lasted only a few hours which laid the foundation for urgency in time and compromise.

[Chart 1: Schematic diagram of simulation phases]

Phase 1: The Assigned Groups (representing one organization or player), consisting of 5 team members, came together to develop three clauses critical to what they believed should be contained in the ultimate Famine Prevention Plan. This was guided by their preparatory work and background lectures.

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12 Assigned Organizations

African Union Special Technical Committee for Health, Labor and Social Affairs
Intergovernmental Panel on Climate Change (IPCC)
African Union Special Technical Committee for Rural Economy and Agricultural Matters
African Union Special Technical Committee Natural Resources and Environment
African Union Special Technical Committee on Trade, Customs and Immigration Matters
The Joint United Nations Program on HIV/AIDS (UNAIDS)
The World Food Program (WFP)
The Gates Foundation
The World Bank
The Pan--African Farmers Forum (PAFFO)
The Food and Agriculture Organization (FAO)
Pan--African Agribusiness and Agro-Industry Consortium (PanAAC)

Phase 2:   Three Assigned Groups then were placed into one Working Group, a collection of organizational allies working in the same sector, but with slightly different priorities. Each Working Group distilled the 9 total clauses from the 3 Assigned Groups down to 5 clauses they agreed were the most important. As the diversity of perspectives widened, the number of compromises increased. The groups were chosen to emphasize tensions of priorities and necessary compromises for completion of an agreement made by the end of each session.

Working Group 1:
African Union Special Technical Committee for Health, Labor and Social Affairs
African Union Special Technical Committee on Trade, Customs and Immigration Matters
The World Bank

Working Group 2:
The Joint United Nations Program on HIV/AIDS (UNAIDS)
The Gates Foundation
The Food and Agriculture Organization (FAO)

Working Group 3:
The Pan--African Farmers Forum (PAFFO)
Pan--African Agribusiness and Agro-Industry Consortium (PanAAC)
African Union Special Technical Committee for Rural Economy and Agricultural Matters

Working Group 4:
Intergovernmental Panel on Climate Change (IPCC)
African Union Special Technical Committee Natural Resources and Environment
The World Food Program (WFP

Phase 3: Each Working Group dispatched one member from each of the Assigned Groups teams to form a Block of 12 players, one from each of the original assigned groups. Each of the four working group brought the five clauses from their discussions in phase 2 to the Block in phase 3. Each Block decided on ten of the 20 clauses to be their proposed final Famine Prevention Plan. At the end of phase 3, five different famine prevention plans existed for review. The FPPs were built by the different clauses that survived through the various phases of negotiation.

The divergent interests represented by each organization forced students to prioritize the clauses which contained goals they would not compromise on, and surrender, combine or change others that they did not feel were as important in relation to their organization. The strategies and protocols were defined by participant research of their organization. There was no assigned leadership structure so that team dynamics could emerge organically through the process. The simulation rules dictated that only a certain number of clauses from each phase would survive to the subsequent phase of the exercise.

Phase 4: All 42 participants reconvened with a representative from each block and were given 3-4 minutes to present their plan to the entire conference. Each player then voted on which plan best reflected the clauses from their Assigned Group. The main outcomes of our simulation were the final five Famine Prevention Plans (FPP) and the final vote on each plan. The students then voted for the plan they felt most accurately reflected the interests of their Assigned Organization, or simply the FPP they believed most likely to be successful. The process of voting on the final prevention plan was meant to allow students the opportunity to see how negotiation skills could result in a variety of outcomes.

Feedback and Evaluation

Evaluation for training programs can be divided into four levels: evaluation of reaction, learning, behavior and results.[15] Our evaluation focused on the evaluating reactions. This signals the comfort of the learning environment and allows for improvement of future simulations driven by student feedback. This does not indicate the extent of learning or outcomes of the simulation. From our evaluation of reactions, we learned that students enjoyed the process and believed that they improved their negotiation skills and understanding of governance processes. The students indicated that we should have left more time for the simulation and shortened the time for preparation lectures. They liked the interdisciplinary topic of the simulation and agreed that the preparation materials were sufficient and written assignment was a good exercise to complete before the conference.

DISCUSSION: DESIGNING SIMULATIONS FOR GLOBAL HEALTH

Asal and Blake posit that to design an effective simulation, 9 questions must be addressed. We will structure our discussion in Asal and Blake's framework and additionally discuss evaluation strategies.[16]

1. *What are your educational goals?* Creators should decide which level of students they are targeting in the simulation so that they design appropriate objectives. For advanced students, objectives should be focused on acquiring or consolidating skills rather than knowledge attainment. For less advanced students, a simulation could focus on content, in which objectives would be more knowledge based. Extent of preparation, complexity of participant interaction and requirements for outcomes can be altered to suit the needs of the student. Defining specific objectives to address this level of student will can help develop evaluation strategies that can measure knowledge attainment, behavior and outcome. We designed our intervention for beginning to intermediate students who would benefit from knowledge and skill development. This was meant to be among their first exposures to global health governance.

2. *What kind of time and technological limitations will you face?* Timeframe: Length of the scenario determines the structure and complexity of the simulation and negotiations. Our simulation lasted for the course of the weekend, but

other simulations could last for one classroom session or for the course of the whole semester.[17][18] Longer simulations allow for development of teams to build deeper understanding of the organization they are representing, as well as depth and breadth of knowledge and skill acquisition. With deeper understanding of organizations, motivations and interests, scenarios can be allowed to develop over the course of months. New inputs may be developed from the facilitator to push students to consider alternate approaches to the project they are working on, or encourage problem solving skills. A longer time frame allows for observation of various skills development such as negotiation, oral presentation, and for more feedback from educators.

Technological Platform: Many simulations are held in person, but another space could be an online forum. This would allow for participation from a variety of geographic locations and educational backgrounds and possibly greater time for contemplation and research for each player's actions. Asal and Blake describe ICONSnet, an online tool to build a simulation.[19]   If simulations are completed through a web-based forum, participants can track their communication and analyze the interactions afterwards.

3. *Will you use a real or fictional case?* Choosing a real case or a fictional case determines the complexity and outcomes of a simulation. A historical scenario can be used for more advanced students to help them discover new content in a well-known case or to compare their outcomes to those of the real case. We chose a fictional scenario, as our participants were relative beginners. This removes bias that may result from a known outcome and maintains focus on theory of political processes and critical analysis of these processes.

4. *What is your level of complexity?* The flexibility of the processes of simulation is vast and can change according to the level of the participant. To increase complexity in our simulation we could have developed a coalition building phase, in which participants decide who they want to partner with amongst the other organizations. Other simulations could increase the constraints on participants in terms of what type of clauses they may develop or could define the goals of each organization more rigorously.

5. *How many participants will you have and how will they be organized?* We wanted our simulation to include interdisciplinary participants and selected those who had demonstrated interest and experience in global health education or fieldwork. We required preparation for the simulation to allow students to learn about the history of organizations as well as current events in global health and to analyze past decision-making events. The simulation offered the opportunity to engage this knowledge in an active process in which they gained insight into motivations, behavioral constraints, resources, and interactions among institutional actors. Furthermore, it allowed students to gain skills in negotiation, learning about the strategic environment, various constraints, and the dynamic give-and-take process. Students are able to realize the constraints of organizational rules and decision-making procedures through the process of achieving their goals under such

constraints.[20] These are useful educational processes for learning about the politically dynamic environment of global health governance.

6. *How will you define the decision-making process and actions within the simulation between teams?* This is the core of active learning in simulations. Our decisions were made between teams as groups merged and players interacted with each other. This embodied the process of negotiation and revealed tensions that might exist between competing interests concerning the same issue. The amount of control that each of the players have in their actions can change the dynamics of the simulation. For example, if participants are allowed to give each other aid or grants or make alliances, this can change the interaction amongst the players who may consider working together or competing for money. Our actions were simple in that organizations were only allowed to remove or add clauses to the Famine Prevention Plan. On the other hand, if donor organizations had given the final votes for the plans that would get funded, this might have influenced the strategy of negotiation.

7. *What kinds of outcomes will you have, structured or open-ended?* The main outcome of our simulation was the Famine Prevention Plan, and the vote at the end of the simulation. However, analysis and de-briefing of the process of the simulation can be another outcome as this can contribute to active learning. De-briefing allows for reflection of the process, which can be lost during the event. With structured questions that promote reflection about the events of the simulation, this could allow time for another perspective of the experience that was not possible while participating. In medical education, reflection on clinical learning cases contributes to retention of lessons learned in each case, and also promotes maturity in understanding of one's own profession.[21] Space and time for critical reflection can be given through required journal entries, a reflection piece with guided questions, or a discussion session at the simulation.

    Critical reflection adds an additional level of analysis, as it promotes inquiry into current organizational and systematic structures and allows students to question the validity of these structures.[22] Schön described his concept of reflection-in-action as involving real time, "on-the-spot surfacing, criticizing, restructuring, and testing of intuitive understanding of experienced phenomena."[23] In the process of learning about global health structures, students who have the opportunity to critically reflect about the processes will be trained to do this in their professional lives as well. It is important for the leaders of the future, not only to learn about the structures, but also be able to question and change the way programs and policies are developed. This may be one of the most important benefits of experiential learning so that students are able to enter their professional field with skills to critically assess structures and make changes.

8. *Will there be any constraints on participants? If so, what kind?* Constraints, such as resource limitations or prescribed preference for outcomes, determine

the nature of conversations during simulations. We put very few constraints on our participants, other than guiding them to advocate for the principles of their organization from their own research and briefs that we put together. Additional constraints could promote a higher level of skill attainment in more advanced students. For example, a second phase of this simulation could include budget allocations for each of the clauses so that they could decide how much money they could contribute and decide where that money is distributed.

9. *What are the evaluation strategies?* Standard evaluation: Kirkpatrick recommends evaluating learning, skills and attitudes with paper tests and performance reviews. We chose to use self-assessment of skill attainment; students felt that they gained understanding of the global health landscape, the internal workings of policy-development, knowledge about food security, and skills in negotiation. Future simulation can use pre and post-tests to assess objectives and knowledge attainment. This type of evaluation has also been used commonly in simulation exercises.[24]

Peer Review: Adding peer review and feedback can contribute tremendously to the learning value of the simulation. Peer review allows for participants to reflect on their peer's work and give constructive feedback, which also helps in their own learning. Peer review is often honest and less restricted or worrisome than faculty review.[25]

Expert Feedback and Evaluation

Feedback is essential for the development of any skill set. In medical education, structured feedback is used within clinical setting in experiential learning--best practices from this literature can be transferred to feedback for simulations. This requires experts in the field to be present during a simulation to provide comments about students' performance, both pieces in which they performed well and pieces in which they can improve. Elements of good feedback include selecting specific behaviors, decisions or actions and giving comments on why these were productive or how they could have been improved.[26]

For future simulations, faculty members or guest experts (people that have experience working with the organizations in question) could observe negotiation processes during the simulation to assess for skill development, especially for a longer simulation in which they can watch skills develop over time. In the conclusion of the session, we could have also included an expert panel to weigh in on the feasibility, strengths, and limitations of each famine prevention plan and discuss the reasons for the differences in each plan.

Rigorous Evaluation: Future simulations for global health must adopt rigorous evaluation methodologies to enhance their effectiveness. There are a few examples in the literature which use the control group, Kirkpatrick's gold standard of evaluation, which could be important models to follow as the field grows.[27]

CONCLUSION

Historically, professionals working in global health learned through active involvement in the field. As demand for preparatory education in global health increases, methodologies for active learning are required. Simulations can fill this need and help develop the skills necessary to develop new leaders in global health. The essential components required to develop an effective simulation discussed in this article include:

1. Creation of Topic and Goals of the Simulation
2. Recruitment of Participants and Preparation
3. Development of the Simulation Structure (Actions, Decision-Making, Outcomes)
4. Feedback and Reflection Strategies
5. Evaluation of Learning and Skills

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Chart 1: Schematic diagram of simulation phases
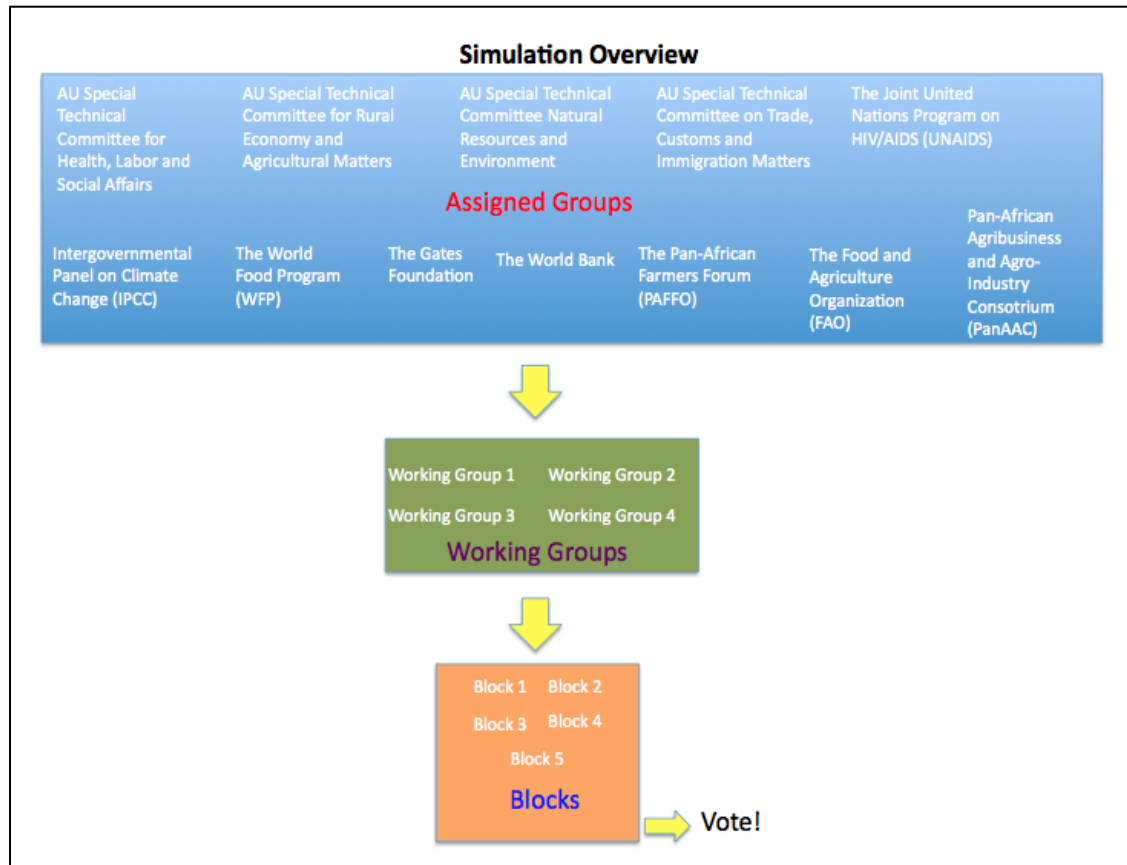
Credit: Robert Tessler

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