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National borders and the spreading of diseases

by Donato Greco¹, MD

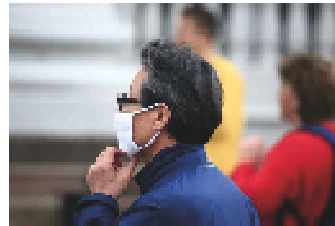
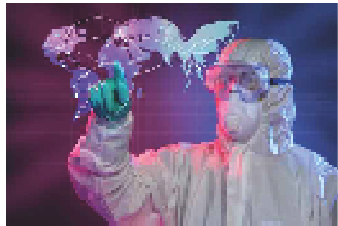
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These last ten years gave humankind a new dimension of health threats!

The traditional division between developed and developing world was obscured by the globalization of population movements: what was considered far came close, the problems of countries hardly known to the wealthy world arrived at our doors; what was considered exotic and curious or a matter of charity action, become a national emergency worldwide.

Political instability, constant conflict and war led to unprecedented migration movement to unprepared countries.

Political and ideological conflict leads to impressive radicalism, so terrorism is here, daily present in our media and well emerging from our own secure towns.



...“what was considered far came close; what was considered exotic and curious or a matter of charity action, become a national emergency worldwide.”

Infectious diseases paralleled this evolution: constantly, at least once every year, new major epidemic threats are arising and finding our countries quite unprepared to respond to events like the SARS outbreak, pandemic flu, Ebola, MERS Co-V...

The truth appears to be as simple as this: as there seems to be no effective solution to cope with the increasing flow of migrants and refugees, there is nothing clear on effective ways to reduce terrorism threats. Some countries are preparing border walls to stop migrants, most countries are developing strong military intelligence to cope with terrorism threats, but what is being done to respond to epidemic threats? What exists rather is a deep lack of knowledge on how to cope with epidemic threats, esp. newly emerging ones!!

European countries became aware of these risks and have recently approved a first tool: **Decision 1082/2013/EU on serious cross-border threats to health**.

Decision 1082 does not engage countries in building walls or addressing useless border screenings nor mass prophylaxis nor population movement restrictions: it is mostly asking countries to build national health preparedness plans and communicate; improve surveillance and alert systems, share experiences with other countries, chose effective communication tools with citizens. This is also how



the ASSET project was borne and is constantly producing updated knowledge on health preparedness issues and the various ways of mobilising the society to understand and support them.

Certainly a European decision and some dedicated research project(s) are not enough to solve a problem with a lot of unknown factors and unpredictable events. However, in my opinion, this is the only effective strategy to cope with future inevitable events with the aim to minimize their impacts: mobilize country awareness and invest in people education and communication is now a must and still more needs to be done to guarantee a safer future for all of us.



Conflicts of Interest during Public Health Emergencies

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An infectious disease epidemic may develop into a public health emergency. Under such circumstances, in order to protect the health of the population, the authorities frequently have to make rapid decisions based on limited information. These decisions have consequences not only on health but also have far-reaching political and economic ramifications, sometimes on a world-wide scale. Clearly, a crisis of this nature must be handled both professionally and ethically. Thus there should be heightened awareness of the possibility that some stakeholders may attempt to interfere in the decision-making process of both national and international health organizations. Conflicts of interest (COI) can lead to bias in studies, to unbalanced decisions regarding resources allocated to specific diseases, and can distort the processes of approving vaccinations and medicines (DeLong, 2012; Nozaki, 2013; Resnik, 2004; Stuckler, King, Robinson, & McKee, 2008).

During various health crises such as the A(H1N1) influenza pandemic in 2009 and the Ebola epidemic in 2013, there was criticism of the way in which World Health Organization

(WHO) managed the crises (Cohen & Carter, 2010).

“Conflicts of interest (COI) can lead to unbalanced decisions regarding resources and can distort the process of managing a crisis”.

During the A(H1N1) crisis, questions were raised about potential COI among expert consultants who had financial connections with the pharmaceutical industry and served on the WHO advisory boards and the WHO Emergency Committee (Epstein, May 12, 2011). Such COIs could lead to excessive promotion of vaccinations and medications which could lead to significant financial losses for many countries. In addition, over-promotion of vaccines and medications appeared to have generated fears and concerns among the public (Cohen & Carter, 2010; Epstein, May 12, 2011). Critics claimed that the marketing efforts did not correspond to the reality of the epidemic situation, as many critics expressed. For example, Paul Flynn, a UK politician charged with investigating the handling of the A(H1N1) outbreak for the Council of Europe, said that,



"This was a pandemic that never really was" (Macrae, June 4, 2010).

The problematic management of the WHO did not arise at the moment of crisis, has been described as a result of an overly close relationship between the WHO and the pharmaceutical industry, that was years in the making. This is described in the report on a joint investigation by the BMJ and the Bureau of Investigative Journalism (Cohen & Carter, 2010) that describes the organization's preparations and guidelines for an influenza crisis. It indicates that they were tainted by COIs at the most basic level. For example, according to the report, the 2004 WHO guidelines were based in part on the advice of experts who received consulting fees from the two leading manufacturers of antiviral drugs used against the virus, Roche and GlaxoSmithKline.

During the Ebola crisis, the WHO criticized the pharmaceutical industry. Director General Margaret Chan claimed that the drive for profit was one of the reasons the development of an Ebola vaccine was delayed.

Other voices opposed this line of criticism, arguing that the COIs within the WHO itself were what led to problematic management of the crisis. The WHO was criticized for its "collusive relations" with the pharmaceutical industry, which was one of the problems that led, it was claimed, to the organization's incapacity to oversee the Ebola outbreak (Sentaku Magazine, October 28, 2014).

Drazen (2015) claimed that COIs occur when experts who have financial ties with the pharmaceutical industry serve on public advisory committees in key decision-making positions. Major healthcare organizations had

encouraged greater interactions between physicians and industry in order to bring greater benefits to patients (Rosenbaum, 2015). Another major issue at the center of the concerns around COIs is the authorities' heavy financial reliability on the pharmaceutical industry. According to Shah (November 9, 2011), a group composed of business corporations including Coca-Cola Co and Pfizer Inc., is the world's top source of financing and leadership in the fight against deadly disease. He claims that these corporations' donations constitute nearly 80 percent of the agency's budget, thus exerting influence on the WHO's policies and decision-making and shaping the global health agenda. The result is reflected in the agency's allocation of budgets to diseases (Shah, November 9, 2011). Stuckler et al. (2008) reported that WHO budget allocations were heavily skewed towards control of infectious diseases. Indeed, during 2008-13, WHO's budgetary allocations were heavily skewed towards control of infectious diseases both in Africa, and in the western Pacific region (Nozaki, 2013).

Another major problem related to the COIs is the "revolving door" – a free movement of key employees between regulators and drug companies (Goldacre, 2013). Officials at government regulators may see working for the government as a means of attaining an important position at a drug company.

HOW TO PREEMPT COIs AND GAIN PUBLIC TRUST

Trust is one of the most essential elements in managing and communicating risk to the public (Cvetkovich & Lofstedt 1999; Earle & Cvetkovich, 1995; Lofstedt 2005). It is easy to lose and difficult to win back (Poortinga & Pidgeon, 2005). Confidence in the health



authorities and their public health decisions is tied directly to the perceived independence, transparency, and fairness of the information communicated. At the same time, a lack of trust can change how safety information is evaluated by the public.

In order to increase the public's trust in policymakers regarding decisions on drugs and medicines, the following solutions are suggested. One solution currently employed is called "disclosure." Disclosure ensures that members on an advisory board disclose any connections they may have with the pharmaceutical industry. The problem with disclosure is that this is not enough and studies have not examined if it actually works (Institute of Medicine, 2009). In light of this, DeLong (2012) suggests closing the revolving door between regulators and drug manufacturers, so that officials could not use public service as a stepping stone to lucrative positions in private

industries. DeLong (2012) suggests this waiting period should be extended to at least five years, or, ideally, ten years.

Another suggestion is that if a member on an advisory board discloses any financial or research connection to the pharmaceutical industry, then he will not be able to participate in decision making regarding vaccinations produced by that company. There must be transparency and visibility not only with regard to disclosures, but also with regard to the committee protocols, that must be available to the public. There needs to be quality control of the decision making process of the committees while the crisis is ongoing, and not just after the crisis. It must examine the answers to the following questions: was the decision making process based on facts? Was it based on studies, and if so, who funded them? What other alternatives to the proposed vaccinations were proposed?

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Intentionally caused outbreaks: secrecy vs. transparency

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ABSTRACT

There will always be a trade-off between secrecy and transparency in intentionally caused outbreaks in modern societies. These issues were analysed based on current knowledge, history of biological attacks, countermeasures and policy trends. This article focuses on secrecy vs. transparency issues when dealing with intentionally caused outbreaks, and is based on ASSET's D2.6 report. We conclude that transparency, without revealing vulnerabilities, can best ensure public cooperation and trust.

1. INTRODUCTION

The radius of fear generated by a terrorist attack far exceeds the zone of injury and death. It is a form of psychological warfare whose goal is to bolster the morale of its supporters, and demoralize and frighten its target audience—victims and their sympathizers [1].

Intentionally caused outbreaks are of concern for law enforcement, governments and public health officials globally. The cost and ease of acquirement, production and dissemination of biological materials for intentional, malicious use— such as bacteria, viruses and toxins can be less prohibitive than other threat agents and

may be yet more difficult to trace. Detection is complicated by temporal delays between exposure to the biological agent and development of clinical symptoms. The use of biological materials as weapons is rare, but the consequences can be considerable. Even a hoax event can be an effective means of instilling widespread public fear. Historically, state and non-state actors' use of biological weapons has been very limited [2], but the records leave no doubt that intentionally caused outbreaks are not a new occurrence. The earliest recorded use of biological warfare, from 300BC, involved contaminating water sources with cadavers, whilst later



manifestations involved using plague-infected cadavers during sieges or the distribution smallpox blankets to Native Americans during the North American Indian Wars [3].

In the nineteenth and early twentieth centuries the science of bacteriology widened the scope of biological warfare agents. Biological agents were included as the Geneva Protocol in the Geneva Convention in 1925. In 1972 the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BWC) came into place, and in the 1980s, possible use of biological agents in terrorism became an issue [4]. It is alleged that the terrorist group Aum Shinrikyo attempted to obtain Ebola for bioterrorist use in 1992 [5].

When dealing with intentionally caused outbreaks, governments need to balance the trade-off between secrecy and transparency when addressing the public. This is especially true if a hoax is suspected or if the intentional nature of the attack has not been confirmed. Similarly reduced transparency, for security purposes, can be necessary for scientific results with dual-use potential. Several national and international policy documents describe strategies to mediate the use and impact of biological weapons. However, few of these strategies address the spread of information from numerous sources. Spreading fear and rumours can be as effective as spreading disease [6]. There are arguments both for and against total transparency and in this paper we summarise the main problems with the secrecy-transparency trade-off. We also suggest best practice based on the results from ASSET report D2.6 [7].

2. METHODOLOGY

We used document analysis to create a taxonomic overview of the problem areas. The taxonomy was deductively divided into main categories and developed and populated as a table cross-categorising the problems. In this taxonomy the usual hierarchically structured top-down relationships were traded for a more associative organisation, as many of the problems could not be categorised hierarchically. The document analysis was divided into a historical overview of intentionally caused outbreaks, a review of current knowledge, and a review of main policy documents. The main problem areas were qualitatively described and analysed. The associative taxonomy categorised governance problems under the categories “international” and “national”, as well as the following main problem areas; tension between secrecy and transparency, freedom of research and security, citizen involvement and experts’ decisions. This article focuses on secrecy and transparency problems only.

3. RESULTS AND DISCUSSION

The results showed that several areas are affected in case of an intentionally caused outbreak, and there are arguments for and against transparency and secrecy. The main governance problems related to the tension between secrecy and transparency consisted of problems related to state biological weapons (BW) programmes, international agreements with vague repercussions and loose implementation, dual-use research, stockpiles, biological agent reservoirs and public communication. A division was made between the threat from non-state- and state actors. The use of biological weapons by non-state



actors is a diverse phenomenon and the identification of trends challenging [8]. Many of the states assumed to have biological weapons programmes, capability, arsenals, research or stockpiles deny these allegations disregarding strong evidence, and no states have official and transparent offensive programmes [9].

Even if the probability of a bioterrorism event is low, the “dread risk” is high as such events cause larger distress in the population than e.g. individual deaths occurring from car accidents [1]. Policy makers should deploy a multi-layered approach to counterterrorism that does not rely on prevention alone, but also monitor terrorists with access and knowledge of biological threat agents as well as planning mitigation measures in case of attack [10]. However, a threat actor can change their behaviour and plans based on known countermeasures and risk analyses can be faulty if they do not take into account responsive behaviour. Efficient biological preparedness and response relies on collaboration between several fields; human and veterinary medical, public health, first responders, police, researchers, policy- and decision makers as well as government bodies [1; 11]. A large part of the trade-off between secrecy and transparency is about mitigating dread effects of intentionally caused outbreaks.

Another case against transparency relates to dual-use issues. Dual-use research and technology refers to research and technology development (RTD) for civilian purposes that may also be used for malicious purposes. Experts have determined that dual-use technology makes biological threat agents more accessible [2; 11]. Designing biological threat agents is no longer reserved for highly skilled scientists, but open to “grass-roots

biohackers” [11]. Researchers and academics need to carefully consider alternative uses for their results before publishing, as seen with the debate around two 2012 influenza research publications [12]. The principles of transparency, discussion and debate for civilian scientific research do not support a restrictive view and it was finally decided to publish the articles in full despite the dual-use potential.

It is difficult to determine whether or not research results sometimes should be fully or partially classified. Responsible research and innovation (RRI), aims to align research and innovation to the values, needs and expectations of the society. A compromise between secrecy and transparency is necessary to fulfil the process of RRI and to avoid making society more vulnerable to attacks in the context of intentionally caused outbreaks. Communication is paramount in both the preparedness and response phase of an incident, and that transparency without compromising, i.e. revealing weaknesses, is the goal [13].

Public communication needs take account of experts’ assessments and advice, and recognise that addressing the issues openly and honestly will aid the continued trust in governmental and public institutions, keep people from making rash decisions and ease the handling of the people who may or may not be affected by the outbreak. Information can help people reduce health risks, limit adverse social and psychological effects and maintain trust and confidence in the official services, indicate protective actions to help reduce morbidity, mortality and the level of disorder [14; 15; 16]. If the fear and dread of the outbreak remains unaddressed, people will lose faith in the government and be prone to counteract



government advice. Therefore, a balanced compromise between secrecy and transparency is ideal to reduce societal vulnerability to intentionally caused outbreak

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