The Role of Research in Policy and Practice: The Zika Phenomena in Puerto Rico

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On April 19, 2017, the 37th Medical Sciences Campus Annual Research and Education Forum opened with the discussion panel The role of research in policy and practice: The Zika phenomena in Puerto Rico, with Dr. Cruz M. Nazario Delgado, Dr. Carmen D. Zorrilla and Dr. Luis A. Bonilla Soto. In this article, we critically examine the public policy process of the Zika epidemic in Puerto Rico, as presented by authors Nazario and Bonilla. We argue that policymaking and the public health responses to confront the Zika epidemic in Puerto Rico took place in a political environment where different US and local actors operated to advance their goals and vision, undermining the role of knowledge, evidence and past experiences. We propose a bottom to top preventive and community empowerment approach to control the vector. This model must be built on successful policy implementation experiences with epidemics in the Island and strengthened by evidence, international guidelines and ethical principles. [P R Health Sci J 2018;37(Special Issue):S33-S40]

Key words: University of Puerto Rico, Zika, Evidence-based policymaking, Political economy of epidemics

Research-informed policies are necessary for effective health systems. Ethical questions, on the other hand, arise in the politics of the policy process when issues of democratic participation in government are valued. Although there are different policy-making models, and not all require a linear sequence in the steps that tie evidence with implementation, research should be able to make a contribution in at least three phases of the policy-making process: agenda setting, policy formulation, and implementation (1). In our assessment of the Zika phenomena in Puerto Rico during 2015 and 2016, we identify three dynamics that constrained these contributions: 1) policy and practice decisions were not always based on scientific evidence related to the Zika virus or historical information of public health experiences in the Island regarding vector-borne disease management; 2) policy development was a top-bottom process dominated by a conservative rhetoric and lacked the participation of concerned stakeholders; and 3) local and international communication outlets that spread misinformation about Zika, played a central role in establishing different patterns of thought among different groups, favoring strategies of some groups over others.

Overview of the Zika epidemic

Zika is a vector-borne viral disease transmitted in the Americas by mosquitoes of the genus Aedes. The virus was discovered in Uganda in 1947. Epidemics appeared in Africa, the Americas, Asia and the Pacific (2). On February 1, 2016, the Director-General of the International Health Regulations of the World Health Organization (WHO) convened its Emergency Committee on Zika to gather advice on the severity of the spread of the virus in Latin America and the Caribbean. The 2015 clusters of microcephaly babies in Pernambuco, Brazil, born from mothers infected with Zika during pregnancy, was considered an “extraordinary event and a public health threat to other parts of the world”. Although the expert committee members acknowledged that there was no scientific evidence, they strongly suspected a causal relationship between Zika infection during pregnancy and microcephaly. An emergency was declared and aggressive vector control measures and personal protective measures to reduce the risk of exposure were recommended (3, 4).

Two weeks after the WHO’s emergency meeting, the United States Centers for Disease Control and Prevention (CDC) published a Special Report in The New England Journal of Medicine (5). The authors quoted various studies.
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Methods

The overall theoretical framework of this article is political economy which, applied specifically to the health sciences, explicitly addresses economic and political determinants of health and the distribution of disease within and across societies, including structural barriers to people living healthy lives. It focusses on the institutions that generate the decisions that create, enforce and perpetuate privilege and inequality and are therefore identified as the sources of social inequalities in health. As suggested by Mosco (10), the dimensions explored from this perspective are history, the social totality, moral philosophy, and praxis. Key themes in this model are social justice, democracy, and the redistribution of power, resources and decision-making.

We also use the evidence-based policymaking process discussed by Bogenschneider and Corbett (11) in which researchers are knowledge producers and policymakers are knowledge consumers in an intimate collaborative effort. This type of symbiotic Mutualistic relationship will bridge the gap that actually exists between both groups in a positive situation that could bring great benefits for the people of Puerto Rico.

Discussion

Lack of scientific evidence affects policy and practice decisions

The WHO Emergency Committee on Zika recommended in its first meeting to enhance surveillance instruments for microcephaly and Guillain-Barré syndrome and to conduct additional research to determine if there was a causative link to Zika virus and/or other factors or co-factors. They also recommended “aggressive measures to reduce infection with Zika virus, particularly among pregnant women and women of childbearing age” (4). This forceful statement was based on the Brazil cases, as presented in a research paper that was eventually questioned by the country’s Ministry of Health. Because the clustering patterns of Zika infection did not correlate with the patterns of microcephaly occurrence, there was suspicion that other factors could also be involved (12). Matto Grosso, for example, had a high incidence of Zika infection (558.1 per 100,000 population) but a low frequency of microcephaly (11.7 per 10,000). In contrast, Pernambuco had a low incidence of Zika infection (5.3 per 100,000 population) but a high frequency of microcephaly (5.3 per 10,000) (13).

It is important to take preventive measures at an early stage of an epidemic before it reaches a peak in the number of cases, but these should not bring unnecessary harm to the groups at risk. In its first meeting, the strategies recommended by the expert WHO panel would eventually have negative consequences when the media unleashed a fear campaign (see below) based, at that moment, on a disputed causal link. Alarming messages and programs were directed mainly to poor women whom were encouraged to make changes in their sexual and reproductive behavior to stop the epidemic. A total of 40,562 cases of Zika were registered during the whole period (9).

By December 31, 2015, the CDC reported autochthonous Zika infections in Puerto Rico by announcing the first case of Zika registered by the Puerto Rico Department of Health (PRDH). Almost one year later (December, 8 2016) the United States Department of Health and Human Services declared a public health emergency in the island, warning women about the risks to their babies of a Zika virus infection during the pregnancy period. The first case of Zika associated with microcephaly was registered in October 2016. During the peak of the epidemic, 38 cases of congenital defects were identified and 69 cases of Guillain-Barré syndrome (7).

The first actions regarding Zika in Puerto Rico were taken in an effort to contain the spread into the continental US. Three months after the announcement of the first case of Zika, the CDC intervened to coordinate aerial spraying of Naled, an insecticide used to quickly eliminate the adults of the Aedes aegypti mosquito in a large area (8). The Director of the CDC, Tom Frieden, met directly with the governor of Puerto Rico, Alejandro García Padilla, to discuss the strategy. The Puerto Rican government had already established its local consulting group, the National Alliance to Fight Zika, under the leadership of the State Agency for the Management and Administration of Disasters (AEMEAD, for its Spanish acronym). The head of the group was the chief of both the AEMEAD and the Fire Department. In due course, the governor requested the US government to declare a Zika epidemic in Puerto Rico, an anticipated step in order for the US Congress to release funds to stop the epidemic.

The Government proposal for the aerial spraying with Naled was met with protests and an educational campaign organized by representatives from the scientific, academic, professional, agriculture, cultural, religious and other sectors who came together as the “Frente Unido Contra la Fumigación Aérea” (United Front Against Aerial Spraying). Based on solid research, this coalition opposed the use of Naled and proposed other public health strategies recommended by the WHO and used in the past in Puerto Rico. Spraying was halted and the CDC and the Puerto Rican government redirected the strategy towards pregnant women. In May 2017, when only 10 new cases of Zika were reported in the island, the PRDH declared an automatic end of the epidemic. A total of 40,562 cases of Zika were registered during the whole period (9).

correcting the findings from a Brazil case report and others about fetuses with microcephaly in pregnant women infected with Zika. They concluded that the virus can cause the condition and other severe brain anomalies. On August 15, 2016, President Obama requested 1.9 billion dollars for Zika research and vaccine development, but only 1.1 billion were approved by the United States Congress after a long period of partisan disputes. During the debates, the Republicans voiced their desire to redirect existing funds and keep them away from Planned Parenthood clinics in Puerto Rico. Democrats wanted a bill without such restrictions in the case of Puerto Rico (6).
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In Brazil, the rate of abortions increased while the Ministry of Health was still looking at other potential causes of the microcephaly cases (12).

In Puerto Rico, after the government was compelled by the public opinion to abandon their plans for aerial spraying with Naled, it refocused the Zika problem on women and pregnancy. This was basically a reformulation of the government’s public health policy. Poor women participating in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) were visited by Puerto Rican government officials, who coordinated with and contracted private companies to spray their homes with the insecticide deltamethrin. These women were asked to sign a waiver of liability that established that the government would not be responsible for health effects caused by the insecticide (Figure 1). This violation of basic rights goes hand in hand with the stigmatizing labels of the young, single and sexualized women living in poverty in Puerto Rico and seems to be justified by blaming them for their own misfortunes.

Again, these policies were not based on evidence. The Puerto Rican public was informed that infected pregnant women had 50 times the risk of having a baby with microcephaly. This claim was based on an article published in The New England Journal of Medicine in which its CDC authors used various frameworks to assess existing research on Zika and microcephaly, including biological plausible explanations. One of the studies analyzed by Rasmussen and colleagues (5) was conducted in the French Polynesia by Cauchemez and colleagues. Based on mathematical models, it presented important limitations such as a small sample size (the baseline prevalence was two cases (0-8) per 10,000 neonates) and a low (30%) participation rate. The authors stated clearly that “extrapolation of our findings to other settings should be approached with caution” (14). On the other hand, Rasmussen and colleagues (5) alerted that, even though the Zika infection hypothesis met four of the seven Shepard’s Criteria for Proof of Teratogenicity, there was still a need to identify factors that modify the risk of an adverse pregnancy outcome such as co-infection with other virus, preexisting immune response to another flavivirus, genetic background of the mother or fetus, and severity of infection. The government and health officials in Puerto Rico used this type of research to establish health policy about the risk of microcephaly and ignored specific recommendations regarding the interpretations of the results.

Nazario C. (13) considers that inferences made from a study with such limitations is highly questionable, particularly when many cofounders of the association were not introduced in the study.

When the Zika emergency was declared in Puerto Rico, the government lacked the baseline data from which to calculate excess risk of microcephaly due to Zika infection. After 2005, and following CDC’s recommendations, microcephaly was eliminated from the list of conditions of the newborn in the
Table 1. Number of live birth with congenital abnormalities (anencephaly and microcephaly) in Puerto Rico.

<table>
<thead>
<tr>
<th>Year</th>
<th>Anencephaly*</th>
<th>Microcephaly†</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>11</td>
<td>nr</td>
<td>Informe Anual de Estadísticas Vitales. 2006 Secretaría Auxiliar de Planificación y Desarrollo. Departamento de Salud de Puerto Rico, San Juan, Puerto Rico. 2010</td>
</tr>
<tr>
<td>2010</td>
<td>6</td>
<td>nr</td>
<td>Sistema de Vigilancia y Prevención de Defectos Congénitos de Puerto Rico. Informe Anual 2014. Departamento de Salud de Puerto Rico. 2014. This report offered the total number of babies born with anencephaly (n=82) for years 2008-2012.</td>
</tr>
<tr>
<td>2011</td>
<td>82</td>
<td>nr</td>
<td>The PRDH (Dr Julio Cadiz) offered the number of microcephaly cases for the years 2013, 2014 and 2015 at a press conference. 11 julio 2016. El Nuevo Día</td>
</tr>
<tr>
<td>2012</td>
<td></td>
<td></td>
<td>The PRHD reports that 522 babies have been born from Zika positive women and the babies were not microcephalic. El Nuevo Día 20 de octubre 2016</td>
</tr>
</tbody>
</table>


Birth certificate (15). Since then, epidemiologists, clinicians and policy makers have no reliable population-based data on the historical trend and current occurrence of microcephaly in Puerto Rico. One of the authors extrapolated data from various reports to study the trend of microcephaly. In Table 1, the number of babies born with anencephaly and microcephaly was obtained from available sources. The limitations caused by the sparsity of information and the lack of uniformity in the reports need to be solved if we want to be able to estimate the expected number of microcephaly cases. The excess risk of the condition due to Zika infection is still unknown but we do not believe that it is in the thousands of cases, as it was communicated by those using inflated numbers to “psychologically torture women that dared to become pregnant” (13).

Health policy concerning epidemics and the management of infectious diseases in Puerto Rico could benefit from the interpretation of information and data of past experiences. As policy advisors, the academic sector should use information and the evidence that history offers. With its use of both, quantitative and qualitative data, history has been called “the evidence based discipline par excellence” (16). There are over 30 years of information in the island, since the first case of dengue in 1925, and data on the management of three different infectious diseases transmitted by the Aedes aegypti mosquito.
Public health policies relied on community-based and individual preventive strategies to eliminate the mosquitoes’ habitat. Never before, during several epidemics of dengue and chikungunya, was aerial spraying considered by the PRDH, precisely because of a lack of scientific evidence about its effectiveness. Rigau and Clark (17), to mention one paper about the Puerto Rican experience, concluded that aerial spraying was ineffective and, furthermore, created a false illusion that the government was in charge and that the community had no role to play in prevention. In the past, the CDC has neither recommended the use of aerial spraying until the recent Zika epidemic, which compels us to pose the question, Why now?

The policy-making process in the colonial territory: the top-bottom way

Knowledge development and policy-making to address the problems of the Zika epidemic in Puerto Rico were ideological and political dynamics influenced by the colonial relationship of the island with the United States. The discourse within the local policy scenario, followed the rhetoric of federal agencies and was used to advance the interests of several government officials, politicians and private corporations. The island’s economic crisis was related to poverty, poverty with mosquitoes, mosquitoes with Zika and Zika with microcephaly. Environmental justice principles were not considered in public discussions (18) as well as the guiding principles for environmental health policy making (19). Problems were attributed to local residents, including the colonial administrators.

Pesticide spraying technologies were presented by the CDC and the Environmental Protection Agency (EPA) as life savers, but in reality they were a created need, based on wrong premises, to justify their use. Naled was opposed by environmental protection and public health advocates in Puerto Rico, with evidence of its harm to people, flora and fauna. Still, it was almost imposed on the Puerto Rican government by the CDC and the EPA general administrators and was meant to prevail over more effective strategies recommended by international organizations. There is convincing evidence of substantial amounts of unnecessary care in the United States when new technologies are accepted as a result of industry influence rather than proven efficacy (20). Their effectiveness is not necessarily proven, but are sold and put to use during decades. Eventually they are withdrawn from the market when research confirms their uselessness. By then, companies have made significant profits (21). It is our position that some of these dynamics were at play during the Zika virus epidemic in Puerto Rico.

The decision to spray with Naled was made at an early stage of the epidemic by the CDC and informed to the governor of the island. During a visit, the federal government officials downplayed the capacity of the local health department by demeaning its surveillance system and control measures. Positive past experiences with primary care strategies seemed to be erased when the CDC vector control expert, Audrey Lenhart, said that “here in Puerto Rico, we’re really starting from square one” (22). A series of events shows how the US government, in agreement with the government of Puerto Rico, undermined the participation of interested groups and violated organizational and ethical principles. A disturbing situation, that eventually pressed the municipality of San Juan to sue the CDC, the EPA and the Puerto Rican government, occurred during a meeting organized with CDC representatives where they informed that spraying with Naled would begin soon. The meeting had been organized by the governor’s interagency committee, the National Alliance to Fight Zika. Some members rejected the plan but were told by the CDC visitors that the agency would carry out the spraying with or without the consent and cooperation of the local authorities (23).

The top-heavy specialist approach in the policy-making scenario and lack of organizational coherence characterized by the tertiary care model have been a focus of critiques of the US health care system. Bodenheimer (20) describes it as a non-system and dispersed model that results when your aim is curative and health care resources are not well matched to the prevalence and incidence of health problems in the community. He calls for a stronger role for community-oriented primary care, the “model that bridges the medical and public health approaches”. Some members in the interagency group understood this vision of a healthcare system and eventually succeeded in their efforts to stop aerial spraying. Two days after the lawsuit brought against the CDC, under the Endangered Species Act and the National Environmental Policy Act, “to prevent defendant The Centers for Disease Control and Prevention to implement its plan to carry out spraying within the San Juan territorial jurisdiction and across Puerto Rico...” (23), governor García Padilla withdrew his endorsement to the CDC’s aerial spraying plan.

Local politics were also in disarray during this epidemic, with frictions among parties with different interests. Poor policy decisions resulted when the governor placed the management of the Zika epidemic under the jurisdiction of the Director of both, the AEMEAD and the Firefighters Department. With this, the PRDH lost a function that is granted by the Organic Law of Puerto Rico’s Department of Health to oversee the implementation of the public health agenda concerning an epidemic caused by vector-borne diseases (24). The AEMEAD was now responsible of developing the State Comprehensive Plan for the Prevention, Protection and Control of Vector-borne Diseases and Other Purposes (25), yet the plan was never made public, and it seemed plausible that it would never be. Another awkward decision came through Executive Order OE-2016-037 (26), that created the Vector Control Unit within the Puerto Rico Science, Technology and Research Trust. As a non-profit organization that serves as fiscal and administrative agent, the unit eventually received a total of $65 million dollars from the CDC, without much red tape from the government.

Again, the PRDH’s was stripped of its powers related to the surveillance and control of vectors through an action that raises serious ethical considerations regarding the roles of the persons...
The local media then portrayed official information that was highly inaccurate and misleading. Following the announcement of the epidemic by the governor of Puerto Rico and the request by the CDC for federal funding, Zika was given special coverage in the international and local media, with events described on a daily basis. A “disinformation epidemic” (13) was underway in anticipation of what had already been decided by the CDC for Puerto Rico: mosquitoes (and people) would be sprayed with Naled. A propaganda campaign was unleashed in Washington DC by portraying the island as the next hot spot for Zika that would likely result in 700,000 Zika reported cases (32). The local press quickly announced the constitution of the interagency group, the visit of the experts from the mainland, President’s Obama feelings about how Puerto Ricans were dealing with the problem, and even the possibility of having the National Guard helping out in the fight against the mosquito. Thousands of residents — including up to 50 pregnant women — were alleged to be infected each day. Hundreds of infants could be born with microcephaly according to government officials (33). As mentioned above, only 40,562 cases where registered during the epidemic in Puerto Rico, well below the 700,000 of expected cases announced in the press.

The fear campaign took a turn when the plan to spray the island was halted. As mentioned, young or pregnant women became the center of attention in response to a need to reformulate the Zika public policy. As in Brazil, the campaign that was developed criminalized sexual relations and pregnancy, making women feel guilty if or when they didn’t consider changing their practices to avoid risks of exposing the fetus to this threatening disease. Photographs of pregnant women appeared daily in the press while the PRDH recommended that they postpone having children because they would put their child at risk. These women didn’t even have Zika and they were becoming fearful of abnormalities in their unborn children. Pregnancy was practically criminalized among poor women who were the target of the government’s educational campaigns. Early during the campaign doctors perceived a dramatic increase in abortions but research on this topic is pending.

Conclusions

During the 37th Medical Sciences Campus Annual Research and Education Forum, authors Bonilla L. and Nazario C. triggered an important debate about a critical problem related to research and its use in the management of the Zika epidemic in Puerto Rico. Research is central in the policy-making process and the academic sector has an important role to play so that politicians and government agencies are well informed. It is also important to make concerned parties understand that campaigns of fear are not effective in changing individual health behaviors and advocate for strategies to manage infectious diseases through on-going primary care prevention activities that emphasize education and empowerment of the affected communities. There are lessons to be learned from the emergence of this new
Resumen

El 19 de abril de 2017, el 37mo Foro Anual de Investigación y Educación del Recinto de Ciencias Médicas abrió con el panel de discusión The Role of Research in Policy and Practice: The Zika Phenomena in Puerto Rico, con la participación de la Dra. Cruz M. Nazario Delgado, la Dra. Carmen D. Zorrilla y el Dr. Luis A. Bonilla Soto. En este artículo hacemos un análisis crítico del proceso de política pública de la epidemia de Zika en Puerto Rico, según presentado por los autores Nazario y Bonilla durante el panel. Argumentamos que este proceso y las respuestas para confrontar la epidemia en la isla se llevaron a cabo en un ambiente político en el cual actores locales y de Estados Unidos buscaron adelantar sus intereses, debilitando el rol del conocimiento, la evidencia e ignorando las experiencias del pasado. Proponemos un acercamiento de apoderamiento comunitario para controlar el vector del Zika. Este modelo debe forjarse tomando en cuenta experiencias exitosas del pasado en la isla y fortalecerse con la evidencia, guías de organismos internacionales y principios éticos.

Referencias

13. Nazario CM. 37th Medical Sciences Campus Annual Research and Education Forum – Discussion Panel The role of research in policy and practice: The Zika phenomena in Puerto; 2017 Apr 19; San Juan (Puerto Rico).
22. The Municipality of San Juan and Honorable Carmen Yulín Cruz-Soto in her official capacity of Major of San Juan v. The Center for Disease Con-
trol and Prevention; Tom Frieden in his official capacity as Director of the CDC; the Commonwealth of Puerto Rico; Governor of Puerto Rico, Honorable Alejandro García Padilla; Secretary of the Department of Agriculture, Honorable Myrna Comas; Health Department Secretary, Honorable Ana Rius-Armendariz; Corporation A, B, C, John Doe, Jane Doe. Case 3:16-cv-0232-CCC Document 1 Filed 07/21/16


27. Bonilla L. 37th Medical Sciences Campus Annual Research and Education Forum – Discussion Panel The role of research in policy and practice: The Zika phenomena in Puerto; 2017 Apr 19, San Juan (Puerto Rico).


