Domestic Understanding of the Revised International Health Regulations

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SYNOPSIS

Objective. The International Health Regulations (IHR) (2005) require countries to report potential public health emergencies of international concern to the World Health Organization. Given that in the U.S. federal system, disease surveillance and reporting is a state, territory, or local-level responsibility, we wanted to discern the level of familiarity at the state and local level with the international obligations for disease reporting under IHR (2005).

Methods. We conducted a multisectoral survey of states, commonwealths/territories, and localities to assess basic knowledge of IHR (2005) and potential impediments to implementation. Respondents included both legal and policy experts from departments of health, agriculture, transportation, and homeland security.

Results. Our survey demonstrated that domestic knowledge of IHR (2005) and of the United States' obligations under the regulations is not widespread, particularly in nonhealth sectors. Of the respondents who were familiar with IHR (2005), some noted legal issues as a concern for implementation, but the lack of federal guidance was perceived as a more fundamental impediment.

Conclusion. Considerably more work needs to be done at the federal level to educate and guide state sectors for the U.S. to ensure its fulfillment of international legal obligations.

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In 2005, the World Health Assembly of the World Health Organization (WHO), following almost 10 years of discussion and debate, unanimously adopted revisions to the International Health Regulations (IHR) (2005).[1] These new regulations built upon previous international agreements, including the International Sanitary Regulations of 1951 and IHR 1969, which obligated member states of the WHO to report any cases of cholera, plague, or yellow fever that occurred within their boundaries.[2,3]

The 2005 revision, which entered into force for the United States in July of 2007, reflects disease concerns that have arisen from the rapid increase in global travel and trade in recent years, and attempts to better detect, control, and react to global disease threats. Under IHR (2005), the 194 member states are required to notify the WHO of any public health emergency of international concern (PHEIC), as defined through an algorithm included in Annex 2 of the regulations. Specifically, each country must have the capacity to notify the WHO within 24 hours of assessing a potential PHEIC. The regulations also revise rules for detecting and managing disease at national ports of entry; require the development of national capacity for surveillance, detection, and response to infectious diseases; and set expectations for developing public health response mechanisms to protect individual rights and avoid interference with international trade.[1]

Translating and internalizing international principles of law into a domestic legal system represents a major challenge for any nation. Implementation of IHR (2005) with nations having a federal system of government, especially nations in which the majority of public health regulatory powers lie—by law, custom, or both—with regional governments, poses a particular challenge. Even so, the U.S. was the only nation explicitly to cite federalism as a reservation to IHR (2005). This reservation rested on the fact that in the U.S., diseases are reported first to the local and state public health authorities and then, depending on the disease and threat, are reported voluntarily to the national level (i.e., the Department of Health and Human Services [HHS] through the Centers for Disease Control and Prevention [CDC]).[4] In the U.S. system, reporting to the federal government is a matter of custom rather than overarching law; that is, the federal government does not claim the authority under its inherent plenary powers to collect or order the collection of pertinent disease surveillance data, but instead relies upon state governments to voluntarily report conditions or diseases to the national authorities. The completeness and timeliness of reporting by the states is highly variable.[5]

This U.S. custom for surveillance stands in stark contrast to WHO regulations, which require reporting of a PHEIC within 24 hours to encourage rapid information sharing. Thus, the U.S. system for complying with the WHO standards rests on voluntary state action—with the advice of organizations such as the Council for State and Territorial Epidemiologists (CSTE)—regarding what is appropriate information to be passed to federal authorities. In practice, states normally share important disease information with their federal partners in a timely fashion, often consulting with experts at CDC, yet this custom is not codified into law.

In April 2008, we convened a meeting of experts from CDC, HHS, the Office of the Assistant Secretary for Preparedness and Response, the National Institutes of Health, the Department of State, the Pan American Health Organization, and academic scholars to discuss implementation challenges in the U.S. presented by IHR (2005). Based on this meeting and discussion with CDC, we developed a survey instrument that we hoped would provide useful information to various decision makers tasked with the domestic implementation of IHR (2005) in the context of the U.S. federal system. The objectives of the survey instrument were to gauge state knowledge of IHR (2005) and gather perceptions on impediments to implementation of the regulations. We were particularly interested in ascertaining the degree of knowledge regarding IHR (2005), both within the health sector and in other sectors that might not traditionally be engaged in health regulations, yet could potentially play a significant role in responding to and containing a PHEIC.

METHODS

The methodology, subject recruitment, and all materials distributed to subjects were approved by The George Washington University Medical Center Institutional Review Board (IRB #030828).

Survey

We used an Internet-based survey provider to disseminate our questionnaire to 50 states, five territories, and four large localities during the period June to September 2008. Before field dissemination, legal and policy experts reviewed the survey, which was developed in coordination with the group of experts convened for the April 2008 meeting. In addition, we received technical assistance to ensure the confidentiality of responses. The questionnaire collected five pieces of information: (*1*) state, sector, and realm of responsibility; (*2*) familiarity with IHR (2005); (*3*) perceptions of state responsibilities; (*4*) perceptions

of implementation challenges; and (*5*) suggestions for reducing implementation impediments. All collected data were automatically de-identified through the Internet-based survey provider, and further precautions were taken to ensure that disaggregated data remained confidential.

Sectors

Because of their potential importance in the implementation of IHR (2005), we selected four sectors to receive the survey instrument in each state: health, security, transportation, and agriculture. We identified the respective departments in each state, territory, and select local governments through official state government websites. Where public health agencies were distinct from agencies with authority to regulate or finance health care, we recruited the public health agency. For territories, we substituted port departments where transportation agencies did not exist. For localities, the city environmental department replaced agriculture departments where those were not present. While transportation and agriculture departments existed in almost every state, security departments did not. Homeland security divisions were often housed in emergency management or military affairs departments.

Respondents

In total, five invitations to participate in the survey were sent to each state, territory, and locality. Given the important policy implications of IHR (2005) for disease surveillance, reporting, and response, as well as the legal concerns involving IHR (2005) implementation, both senior policy advisors and legal counsel from the health sector were invited to participate. In the other three sectors, only legal counsel received an invitation to participate. We identified subjects through state/territory/locality websites or directories, or through direct phone calls to the agency, requesting contact information for the appropriate person. Senior policy advisors were usually identified by the state. These figures included such senior public health officials as a state's chief epidemiologist or senior staff within the state or territorial public health agency's epidemiology division. Where an appropriate policy advisor was not identifiable or available, we sent the initial invitation to the state epidemiologist. For legal contacts in the health, transportation, security, and agriculture departments, when more than one counsel was available, we requested a counsel dealing with public health law (for health agencies), preparedness, or regulation implementation (for other departments). Frequently, departments did not retain their own legal counsel and a department's counsel was located in a state attorney general's office.

States/territories/localities

We invited all 50 states to participate in the survey, along with five territories and commonwealths considered to be under the legal auspices of the United States (American Samoa, Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands). We also included four localities (the District of Columbia, Chicago, Los Angeles County, and New York City) in this analysis because they are the only four localities that are consistently considered as a unit of analysis for disease surveillance and reporting.

Analysis

The Internet survey provider collected, organized, and de-identified data automatically and evaluated them both quantitatively and qualitatively. In terms of quantitative analysis, simple ratios and percentages were calculated in Microsoft® Excel to summarize findings and provide a basis for discussion of knowledge and perceived impediments to IHR (2005) implementation. Data were analyzed both in the aggregate and by sector. Refusals to participate were coded according to reason and separated from nonresponses. Comments received through the online survey instrument were analyzed and summarized qualitatively to identify major themes. Because of the type and number of comments, additional coding through other means was not necessary.

RESULTS

Out of 295 possible responses (from five sectors and 59 states/territories/localities), we received a total of 106 responses to our survey request. Of those, 102 surveys contained answers to the first question, "Do you know what the IHR (2005) is?" The other four respondents completed only demographic information. The aggregate response rate for purposes of our analysis was 35% (102/295). The breakdown of the survey response by state, sector, and legal or policy background of respondent is summarized in Table 1.

The 102 responses represented 41 states, four localities, and three territories. These states represented a diverse geographical range, and of the nine states that did not respond, only two border states (i.e., states bordering another country or the ocean) were nonresponsive. Out of 102 respondents, 71 were legal counsel/attorneys, while 31 were policy advisors. The single largest group of respondents was public health agency counsel. Four survey responses from security,

Table 1. Responses to IHR (2005) survey by health-policy, health-law, security, transportation, and agriculture sectors

Measure	*Total*	*Health policy*	*Health law*	*Security*	*Transportation*	*Agriculture*
Total number of responses to IHR (2005) familiarity question	102	27	36	8	14	17
Total number of surveys completed	92	27	35	6	12	12
Percentage of surveys completed (*n*=92)	NA	29	38	7	13	13
Number of nonresponses	161	26	21	40	38	36
Number of respondents who supplied a reason or written refusal for nonresponse	32	6	2	11	7	6

IHR (2005) = International Health Regulations (2005)

NA = not applicable

transportation, or agriculture sectors came from policy advisors, while the remaining 26 responses came from legal counsels. In these four cases, senior policy advisors elected to fill out the transportation, agriculture, or security sector survey due to the fact that (*1*) there was no available/appropriate legal counsel or (*2*) internal conversations within the department prompted this type of individual response.

Table 2 provides information regarding the number of survey respondents who did not know what IHR (2005) was at the time of the survey, as well as how many respondents had received a briefing on the regulations. Results are depicted in percentages to provide a consistent and intuitive way to examine the data, given the variation in sample size by sector. The health sector had a much higher familiarity with IHR (2005), but even among health respondents, 42% of legal respondents were not aware of the regulations. Health departments in three states assumed that IHR (2005) concerned the international adoption of children, and one state health department thought IHR (2005) explicitly concerned food safety. In addition, multiple respondents indicated that they were the only individuals in their entire department or section with knowledge of the requirements of IHR (2005). Of 17 responses that came from state epidemiologists or designees within the epidemiology office, four respondents reported no familiarity with IHR (2005).

Knowledge about IHR (2005) was particularly low in the transportation and agriculture sectors (Figure). Many respondents in these sectors assumed that IHR (2005) was outside their jurisdiction and frequently asked why they were being contacted for a study of health regulations.

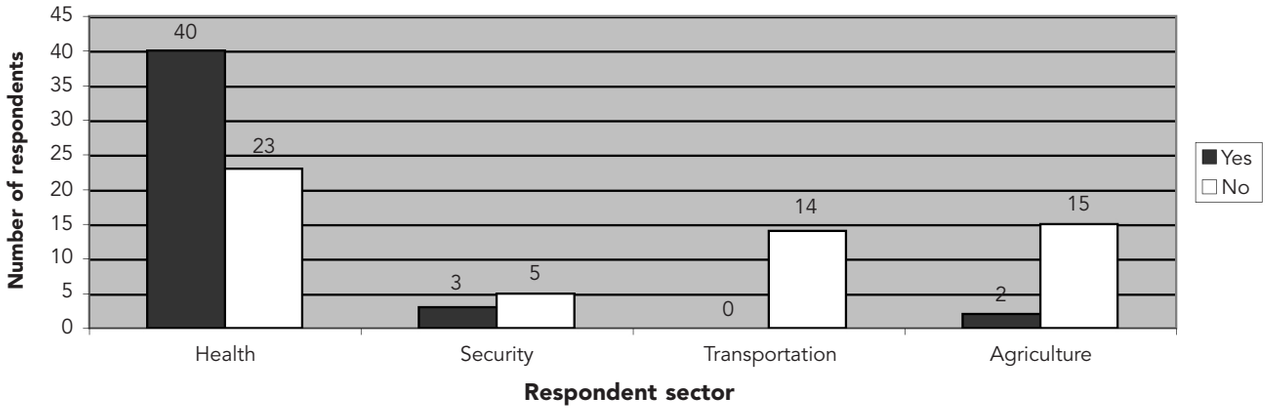
Health was the primary sector to have received any type of information briefing on IHR (2005); one agriculture-sector respondent had received a briefing. All respondents that had received a briefing also knew what IHR (2005) was. Among those reporting receipt of information, the predominant response was that the briefings regarding IHR (2005) came from CDC and CSTE. Additionally, some respondents received information from the Department of Homeland Security, the WHO, and the Association of State and Territorial Health Officials. Among respondents who indicated that they had not received a briefing, only 23% knew what IHR (2005) was. In addition, knowledge of IHR (2005) among those who did not receive a briefing was actually higher in security and agriculture than in either health-law or health-policy sectors, though

Table 2. Percent, by sector, of respondents who knew what the IHR was or had received a briefing about IHR (2005)

Response	*Total (percent)*	*Health policy (percent)*	*Health law (percent)*	*Security (percent)*	*Transportation (percent)*	*Agriculture (percent)*
Did not know what IHR (2005) was (*n*=102)	56	30	42	62	100	88
Received briefing on IHR (2005) (*n*=102)	27	52	36	0	0	1
Did not receive briefing but knew what IHR (2005) was (*n*=74)	23	26	38	100	0	50

IHR (2005) = International Health Regulations (2005)

Figure. Number and type of yes/no responses, by sector, to the question, "Do you know what the IHR (2005) is?"[a]



[a]The health sector was the only sector where there were more "yes" than "no" responses. Not a single respondent in the transportation sector knew what IHR (2005) was.

IHR (2005) = International Health Regulations (2005)

the absolute number of respondents who knew about IHR (2005) was much lower than in the health-policy and health-law respondent groups.

To assess the impediments to implementation, we asked survey respondents to rank the top three IHR (2005) implementation problems they perceived at the state, territory, or local level. Among the 90 respondents who completed this question, the predominant impediment was the absence of informational guidance (Table 3). Nearly three-quarters of respondents ranked "need more operational guidance from federal officials" in their responses, and 31% ranked this impediment their number-one implementation concern. Following this concern was "need specific funding," ranked in any position by 62% of respondents and ranked first by 26% of respondents. Among the three responses related to legal impediments to implementation (e.g., federalism, privacy, and state law), privacy law represented the biggest concern, with more than a quarter of respondents ranking this impediment. Overall, it appears that at least at a threshold point of initial understanding about IHR (2005), clearer guidance and additional funding represented more salient concerns with both policy and law respondents in the states than the legal impediments to implementation.

Open-ended comments regarding implementation impediments tended to be very broad and fell within two general themes: communication/education and available resources. Many respondents suggested that communication about IHR (2005) needed to be improved and that the new requirements of the international regulations needed to be publicized more effectively, particularly by the federal government. Most states offered comments about their intention to make no changes until they had received better communication from federal officials regarding how existing practices would need to be altered.

Respondents noted that offices were not sufficiently trained, and that this training could not occur without funding—the second primary suggestion that emerged from these results. Money/funding was a significant concern among those who gave comments, noting that if funding was not made available for training or personnel resources, the obligations under IHR (2005) would not be met. A number of participants noted recent reductions in CDC grant funding, as well as other priorities that drew funds away from disease surveillance and reporting. Both policy and law respondents focused on concerns about information and funding; we found no systematic differences between the two types of respondents. Furthermore, respondents who reported familiarity with IHR (2005) did not have notably different comments than individuals who had no familiarity with IHR (2005). Those with some familiarity tended to have slightly more nuanced ideas about what exactly needed to be accomplished (e.g., specific coordination activities) and the governmental bodies that should be involved, but education and funding remained key concerns for those with prior IHR (2005) knowledge.

Out of the 90 comments we received about impediments to implementation, 15 respondents indicated that they saw no problem with the existing mechanisms of disease reporting and believed existing state law and reporting procedures were sufficient to meet IHR (2005) obligations. Ten respondents said they perceived

a legal impediment to implementation, particularly relating to issues of federalism (state-to-federal disease reporting) and privacy rights. Some respondents also indicated that the WHO and CDC needed to work on the case definitions of particular diseases for IHR (2005) to be successfully implemented at the state, territory, or local level.

DISCUSSION

Knowledge about IHR (2005) requirements is not widespread; indeed, it appears to be significantly limited. In health sectors, a surprisingly substantial number of respondents did not know what IHR (2005) was, and although CDC has taken steps to educate state and local entities on the regulations (including releasing information in its *Morbidity and Mortality Weekly Report*,[6] posting presentations on websites,[7,8] and giving talks at national public health conferences[9,10]), not enough respondents recalled ever receiving a briefing. CDC's educational efforts may have reached some individuals in the health sector, but knowledge appears not to have penetrated even the highest levels of many state, local, or territorial departments.

This suggests the need for far broader incentivization efforts, such as onsite training, technical assistance, implementation tools, and specific state implementation grants. The lack of knowledge regarding IHR (2005) is particularly surprising, given that it simply updates obligations that the U.S. has had under regulations of this name for 50 years. This lack of awareness underscores the disconnect between state and local entities that identify and respond to public health emergencies, and federal officials who are obligated to adhere to international agreements.

While legal impediments appear to be perceived by the states as a problem in implementation, legal concerns seem to be overshadowed by the impediments relating to the lack of federal guidance or funding for implementation of IHR (2005). In both

Table 3. Survey respondents' ranking of the top three impediments to IHR (2005) implementation, by policy and law respondents

Response (n=90)[a]	*Total ranking impediment (percent)*	*Ranked #1 (percent)*	*Ranked #2 (percent)*	*Ranked #3 (percent)*
Do not understand regulations	46	13	19	13
Policy	48	14	17	17
Law	46	12	20	11
Need more guidance from federal officials	72	31	30	11
Policy	79	34	38	7
Law	69	30	26	13
Need funding to respond effectively	62	26	21	16
Policy	55	28	21	7
Law	66	25	21	20
Legally not obligated (federalism)	19	2	9	8
Policy	14	0	7	7
Law	21	3	10	8
Privacy laws complicate participation	27	7	6	14
Policy	34	3	7	24
Law	23	8	5	10
Other state/city/territory laws constrain participation	8	1	1	6
Policy	7	0	0	7
Law	8	2	2	5
Other	16	6	0	10
Policy	21	7	0	14
Law	13	5	0	8
Not applicable	17	10	1	5
Policy	17	10	0	7
Law	16	10	2	5

[a]The 90 respondents included 29 policy and 61 law respondents.

IHR (2005) = International Health Regulations (2005)

the structured part of the survey and the open-ended comments section, more than half of the respondents pointed to a lack of funding and educational needs as primary concerns.

Nonhealth sectors, particularly transportation and agriculture, were for the most part not previously aware of IHR (2005), and did not perceive that they had any responsibility under the regulations. Some respondents were openly hostile about any suggestion that they might have an interest in a health-related study, and many referred our request for study participation to health departments in their respective locations. This type of response underscores the point that many officials, advisors, and counsel in sectors that are not directly linked to health do not see themselves as playing any role in a health emergency. When a public health emergency does occur, however, the health sector must rely upon these other sectors for information and cooperation. Clearly, more must be done to communicate the role of all sectors of state and local governments in detecting and responding to public health emergencies.

CONCLUSION

The results of this study offer serious policy implications for decision makers in the U.S. federal government. While federal officials within HHS are confident that the U.S. will be able to meet the obligations of IHR (2005) by the custom and practice of public health reporting from state and local entities, this practice is not codified into law. Because familiarity with international obligations for disease reporting might affect state and local decision-making for information sharing, federal officials should consider more aggressive actions to educate the public health community on IHR (2005). Policy impediments relating to operational guidance and funding at the state and local levels must also be addressed. On the issue of engaging multiple sectors in addressing public health emergencies, it appears that more must be done to educate and work with other government sectors on potential roles, responsibilities, and communication strategies in a public health emergency. Only then might the nonhealth sectors develop an interest in IHR (2005).

It will be important to continue research on the implementation of IHR (2005), both within and outside of the U.S. While the adoption of IHR (2005) was monumental in the history of global health governance and international cooperation in the fight against infectious diseases and other emerging health threats, the regulations are only effective if they are implemented and nations are compliant. The only way nations can be compliant with IHR (2005) is if the pertinent actors are aware of their obligations.

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