qrulepubliccomments

From: Nuzzo, Jennifer [jnuzzo@upmc-biosecurity.org]
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To: qrulepubliccomments
Cc: O'Toole, Tara; Inglesby, Thomas; dahzero@aol.com
Subject: Center for Biosecurity's Comments onf Proposed Revisions to 42 CFR 70 and 71 (Quarantine Rules)

Attachments: CBS Comments on Proposed Revisions to Quarantine Rules.doc; EID Border Screening for SARS St John.pdf; PEDS Cost of Containing Measles.pdf; EID Nonpharmaceutical Interventions for Pandemic Influenza Intl Measures.pdf

CBS Comments on Proposed Revis...

EID Border creening for SARS

PEDS Cost of Containing Measle...

EID harmaceutical Inter

Attached please find comments from the Center for Biosecurity of the University of Pittsburgh Medical Center on the Proposed Revisions to 42 CFR 70 and 71 (Quarantine Rules). In addition, three works that are cited in these comments are attached for your review.

Thank you,

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Comments from the Center for Biosecurity of UPMC on Proposed Revisions to 42 CFR 70 and 71 (Quarantine Rules)

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Summary:

The proposed revisions to 42 CFR 70 and 71 (Quarantine Rules) are in many instances inconsistent with available scientific understanding of the nature of person-to-person disease transmission. This is particularly the case with pandemic influenza. 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 flu, is highly questionable and unsupported by data. The proposed revisions fail to take into account the likely direct and indirect costs of implementing the proposed actions, nor is there an adequate analysis of the cost-effectiveness of the proposed revisions. In our view, the proposed rule will do little, if anything, to inhibit transmission of SARS or influenza, will impose significant costs and implementation burdens on local public health agencies, airlines, and travelers, and are likely to impede business, confuse the public and could put in jeopardy the public's current high level of trust in Centers for Disease Control and Prevention (CDC). The authorities that the proposed revisions would grant to airline personnel and to the Director of CDC (e.g. the authority to select persons to be detained in quarantine) are extremely broad and would undoubtedly be highly controversial. We share the CDC's intent to improve the country's capacity to contain epidemics of contagious disease, but the measures proposed in this rule are not the means by which we can build this capacity for reasons including those specified below.

Specific issues:

1) The assumption that we can stop a pandemic illness of SARS or influenza by monitoring air travel is not correct.

A historical review of pandemics indicates shows that travel restriction will not do much to control an influenza pandemic. In an article recently published in *Emerging Infectious Diseases* (EID), the World Health Organization Writing Group concluded that of the available non-pharmaceutical interventions for controlling an influenza pandemic, "screening and quarantining entering travelers at international borders did not substantially delay virus introduction in past pandemics…and will likely be even less effective in the modern era."

A similar conclusion was reached by public health authorities involved in the international efforts to control SARS. In a January 2005 EID article, Canadian health authorities report that "available screening measures for SARS were limited in their effectiveness in detecting SARS among inbound or outbound passengers from SARS-affected areas."[1] A review by the WHO Working Group on Prevention of International and Community Transmission of SARS also concluded that "entry screening of travelers through health declarations or thermal scanning at international borders had little documented effect on detecting SARS cases.[2]

2) **The health benefits of the proposed quarantine rules were calculated for a SARS-like illness and do not generalize for other diseases. Even for a SARS epidemic, the evaluative model provided is far too optimistic.**

The Regulatory Impact Assessment (RIA) of the proposed rule that was completed by Eastern Research Group was only conducted for a SARS-like illness. This particular epidemiological model found that predicted health benefits of the proposed revisions to 42 CFR 70 and 71 are "highly sensitive to the characteristics of the illness being modeled." In SARS, patients are contagious when symptoms are apparent. With flu, the incubation period can be as short as one day and patients may become contagious before symptoms become apparent. As a result, some flu patients will be contagious even before they know they have been exposed. Also, a significant percentage of people infected with and transmitting flu are asymptomatic. Persons exposed to asymptomatic individuals could not be identified**.** The CDC needs to evaluate the health benefits of the proposed quarantine rules in the context of the particular illnesses it is hoping to control.

In the case of the SARS model, the RIA presumed no false positive or false negative cases of SARS. Given the absence of rapid SARS diagnostic tools and the nonspecific clinical hallmarks of this disease, some cases would likely be missed in a real outbreak.

3) **The premise that it is possible for non-medical personnel to recognize a contagious illness such as pandemic flu or SARS and differentiate it from the many other medical conditions that could cause the same symptoms is not correct.**

In the proposed quarantine rules, the CDC says that revising the definition of illness to include general symptoms is necessary to increase the sensitivity of quarantine regulations and to increase the ability of "non-medical personnel" (i.e. flight crews) to recognize ill passengers "without the benefit of medical examination." It is entirely unreasonable to place the burden and responsibility of identifying sick persons on flight crews who have not had medical training.

4) **There is no evidence that broadening the definition of ill persons will improve the ability to effectively contain disease spread. On the contrary, this action is certain to have several adverse consequences, including diversion of scarce public health resources to futile exercises in tracking false positive cases. An accurate cost-effectiveness assessment must be completed for the proposed rules.**

There is no evidence that expanding definition of illness to include nonspecific symptoms and an increased reliance on lay persons will actually identify patients in ways that would substantially reduce the spread of illness within the community. As a point of comparison, a recent study found that the economic costs of tracking and implementing control measures of a single case of travel-related measles exceeded the individual cost of uncomplicated illness by greater than >1000 fold.[3] As the definition of illness that would mandate quarantine is expanded, it is likely that the costs associated with tracing contacts will increase, particularly as false-positives increase by relying on non-medically trained persons (such as flight crews) to identify ill persons.

5) **There is no rationale for changing the mechanism for reporting cases to exclude local health authorities from the initial notification requirement**.

In the current regulations, "the person in charge of any carrier engaged in interstate traffic" must notify local health authorities of a suspected case of communicable disease at the next port of call, "as soon as practicable." Under the proposed revisions to the rules, the requirement that carriers report to local health authorities is eliminated, "requiring instead that reports be made to the Director [of the CDC]" who would "assume responsibility for notifying local health authorities as indicated." The CDC does not have the appropriate resources or the responsibility to be the first responder agency at the local level. Conducting epidemiological investigations and implementing public health control measures will likely be the responsibility of local health authorities, so local public health should be included in initial notification of any outbreak.

6) **Monitoring only interstate flights for patients who need to be quarantined does not make sense.**

To prevent spread of infection between states, why would the CDC single out air travel? Why do the proposed rules not apply to interstate train or bus travel? If preventing ill patients from crossing state lines is so fundamentally important to protecting public health, why only apply this principle to air travel? Since this would be impossible, why single out air travel?

7) **This rule would require the collecting of contact and personal information on the hundreds of thousands, even millions, of persons who take flights every day in America. This should provoke a number of serious concerns.**

What information systems would need to be created for proper and secure management of this? What are the appropriate controls/oversight? It will cause legitimate public concern that government would be able to track citizens' movement and access personal information upon suspicion of a person having a contagious illness or having contact with someone who had a contagious illness.

8) **The rule proposes that arriving persons can be ordered to a medical examination and then placed into provisional quarantine. This element of the proposed rules is highly concerning on a number of levels.**

This places unwarranted authority in a single individual ("the quarantine officer") whose medical training is not clearly articulated in the rule. Who will provide medical attention/care and legal resources for these quarantined individuals? Do these individuals have to get their own counsel at their own cost? The details of the administrative hearing which may follow a three day provisional quarantine period are unclear. Who is the "hearing officer?" Is it a judge? A doctor? What are the rights of the detained/quarantined individual?

9) **The provisions for actions taken in a state of war (Section 28-29) imply authorities that are far too broad and call into question CDC's assurance that it will always provide due process.**

Since we are already in state of war, does this imply that the Director of CDC (or her designee) can currently detain or release persons at will "without making any requisite finding." If so, with no articulated end to the war, this would imply there are no current plans for providing quarantined individuals with due process.

References:

[1] St. John RK, King A, de Jong D, Bodie-Collins M, Squires SG, Tam TWS. Border screening for SARS. Emerg Infect Dis. Available from http://www.cdc.gov/ncidod/EID/vol11no01/04-0835.htm. Accessed January 24, 2006.

[2] World Health Organization Writing Group. Nonpharmaceutical interventions for pandemic influenza, international measures. Emerg Infect Dis. Available from http://www.cdc.gov/ncidod/EID/vol12no01/05-1370.htm. Accessed January 24, 2006.

[3] Gustavo H. Dayan, Ismael R. Ortega-Sánchez, Charles W. LeBaron, M. Patricia.
The Cost of Containing One Case of Measles: The Economic Impact on the Public Health Infrastructure—Iowa, 2004. Available at: http://www.pediatrics.org/cgi/content/full/116/1/e1. Accessed January 24, 2006.