

Brief Comment

Comments from the Center for Biosecurity of UPMC on Proposed Revisions to Federal Quarantine Rules

JENNIFER B. NUZZO, DONALD A. HENDERSON, TARA O'TOOLE,
and THOMAS V. INGLESBY

On November 30, 2005, the U.S. Centers for Disease Control and Prevention (CDC) proposed changes to federal quarantine regulations (42 CFR Parts 70 and 71). As stated in the proposed rules, the intent of changes is “to clarify and strengthen existing procedures to enable CDC to respond more effectively to current and potential communicable disease threats.”¹ Parts 70 and 71 of 42 CFR authorize the Secretary of the Department of Health and Human Services (HHS) to make and enforce regulations “as in his judgement are necessary to prevent the introduction, transmission, and spread of communicable diseases” from foreign countries (Part 71) and between states (Part 70).¹ The Center for Biosecurity of UPMC reviewed the proposed revisions to the quarantine regulations and submitted to CDC the following analysis as its official comments on the revised rules.

THE PROPOSED REVISIONS to the Federal Quarantine Rules (42 CFR 70 and 71)¹ 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 revisions, 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 and to confuse the public and could put in jeopardy the public's current high level of trust in the 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.

Jennifer B. Nuzzo, SM, is an Analyst; Donald A. Henderson, MD, MPH, is Distinguished Scholar; Tara O'Toole, MD, MPH, is Chief Executive Officer and Director; and Thomas V. Inglesby, MD, is Chief Operating Officer and Deputy Director; all are at the Center for Biosecurity of the University of Pittsburgh Medical Center, Baltimore, Maryland.

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 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 nonpharmaceutical 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.”²

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 reported that “available screening measures for SARS were limited in their effectiveness in detecting SARS among inbound or outbound passengers from SARS-affected areas.”³ 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.”⁴

2. The health benefits of the proposed quarantine rules were calculated for a SARS-like illness and cannot be generalized to 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 conducted only for a SARS-like illness.⁵ This particular epidemiologic 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.”⁵ In SARS, patients are contagious when symptoms are apparent. With flu, the incubation period can be as short as 1 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 nonspe-

cific clinical hallmarks of this disease, some cases would likely be missed in a real outbreak.

3. The premise that it is possible for nonmedical 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.”¹ It is entirely unreasonable to place the burden and responsibility of identifying sick people on flight crews who have not had medical training.

4. There is no evidence that broadening the definition of ill people 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 the 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 more than 1,000-fold.⁶ 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 due to the reliance on nonmedically trained persons (such as flight crews) to identify ill people.

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.”¹ 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 epidemiologic investigations and implementing public health control measures will likely be the responsibility of local health authorities, so local public health authorities 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 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 fundamentally important to protecting public health, why apply this principle only to air travel?

7. This rule would require the collecting of contact and personal information on the hundreds of thousands, even millions, of people 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 information? What are the appropriate controls/oversight? It will cause legitimate public concern that government would be able to track citizens' movements and have access to their personal information based on the suspicion of a person's having a contagious illness or having had contact with someone who had a contagious illness.

8. The rule proposes that arriving travelers 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 that may follow a 3-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 a state of war, does this imply that the Director of CDC (or her designee) can currently detain or release people 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.

Submitted January 27, 2006

REFERENCES

1. Control of Communicable Disease, *70 Federal Register* 229 (proposed November 30, 2005) (to be codified at 42 C.F.R. pts. 70, 71). Available at: http://www.cdc.gov/ncidod/dq/nprm/docs/42CFR70_71.pdf. Accessed January 5, 2006.
2. St. John RK, King A, de Jong D, Bodie-Collins M, Squires SG, Tam TWS. Border screening for SARS. *Emerg Infect Dis* 2005;11(1):6–10. Available at: <http://www.cdc.gov/ncidod/EID/vol11no01/04-0835.htm>. Accessed January 24, 2006.
3. World Health Organization Writing Group. Nonpharmaceutical interventions for pandemic influenza, international measures. *Emerg Infect Dis* 2006;12(1):81–87. Available at: <http://www.cdc.gov/ncidod/EID/vol12no01/05-1370.htm>. Accessed January 24, 2006.
4. Bell DM, World Health Organization Working Group on Prevention of International and Community Transmission of SARS. Public health interventions and SARS spread, 2003. *Emerg Infect Dis* 2004;10(11):1900–1906. Available at: <http://www.cdc.gov/ncidod/EID/vol10no11/04-0729.htm>. Accessed April 5, 2006.
5. Eastern Research Group. *Regulatory Impact Analysis of Proposed 42 CFR Part 70 and 42 CFR Part 71: Control of Communicable Diseases Notice of Proposed Rulemaking (NPRM)*. Atlanta: Centers for Disease Control and Prevention; 2005. Available at: http://www.cdc.gov/ncidod/dq/nprm/docs/draft_ria_final.pdf. Accessed March 22, 2006.
6. Dayan GH, Ortega-Sánchez IR, LeBaron CW, Quinlisk MP, Iowa Measles Response Team. The cost of containing one case of measles: the economic impact on the public health infrastructure—Iowa, 2004. *Pediatrics* 2005;116(1):1–4. Available at: <http://www.pediatrics.org/cgi/content/full/116/1/e1>. Accessed January 24, 2006.