

CHAPTER 12

BIOLOGICAL INTERVENTIONS TO CONTROL INFECTIOUS DISEASE:
IMMUNIZATION, SCREENING, AND TREATMENT

International Health Regulations -

- Comments from the Center for
- Law & the Public's Health
-





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The Draft Revised International Health Regulations

Comments from the *Center for Law & the Public's Health*

As of March 3, 2004

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The comments below refer to the proposed revisions to the International Health Regulations (“IHR Revisions” or “Regulations”) outlined in the International Health Regulations Working Paper for Regional Consultations (IGWG/IHR/Working paper/12.2003). *Center* faculty have addressed areas where the IHR Revisions are ambiguous, unclear, or could be improved. Where possible, specific comments related to wording choices and other editorial observations are also provided. We have also suggested several areas where additions or modifications to the IHR may be useful.

Overall, the IHR Revisions largely achieve the stated changes from the existing regulations. The IHR Revisions 1) broaden the scope of reportable public health incidents to include all events potentially constituting a public health emergency of international concern; 2) present a legal framework for a worldwide epidemic surveillance and response strategy; 3) establish a mechanism whereby all States have a designated contact responsible for communicating with WHO; and 4) suggest core surveillance and response capacities required at the national level. The IHR Revisions appropriately focus on early detection of public health risks, regular and open communication between States and WHO, and the use of necessary and reasonable public health measures where diseases may traverse national borders. We applaud those at WHO who have so effectively carried forward this essential initiative for global health.

Definitions. These Regulations must apply to various national systems with different infrastructures and political sub-entities. As a consequence, the definitions must be written so that they can be applied flexibly to the relevant components of national public health laws and infrastructures. The Definitions section (Part I) is useful and necessary for the Regulations, although some of the specific definitions could be improved. The

definitions for “contamination” and “infection,” for example, use these words in their own definition and thus are circular. Additionally, the term “isolation” is used to denote both suspect and affected goods or persons. Typically, isolation is used to mean separation of affected goods or persons, while quarantine is used to mean separation of suspect goods and persons.¹ Since the public health measures warranted against suspect and affected goods and persons may differ, using distinct terms may be useful.

One frequently used term is completely omitted from the Definitions: “public health emergencies of international concern.” Given the importance of this term to the administration of the IHR Revisions, it should be included in the Definitions. A proposed definition could be: **“Public health emergencies of international concern” means an event in which more than one of the following criteria, as outlined in Annex 2 of these Regulations, are met: 1) the event has a serious public health impact; 2) the event is unusual or unexpected; 3) the event poses a significant risk of international spread; or 4) the event poses a risk for international restrictions.**

Purpose and Mission Section. The inclusion of a more explicit “Goals and Missions” section at the beginning of the IHR Revisions could more extensively articulate the purpose of the Regulations and assist in their interpretation and implementation. The current version includes a single sentence purpose (Article 2) that could be easily and effectively expanded to list the purposes relevant to the justification for and implementation of the Regulations. Well-developed sections on purpose or missions may not be substantively binding, but they can have a beneficial explanatory effect. Rather than focus on minimizing interference with trade, the mission statement should express the salience of WHO’s health mission, as well as the protection of human rights. Faculty at the *Center for Law and the Public’s Health* has experience in drafting mission statements. See, for example, Section 2-101. Mission Statement of the Turning Point Model State Public Health Act, and the Preamble to the Model State Emergency Health Powers Act (both of which are available at <http://www.publichealthlaw.net/Resources/Modellaws.htm>).

Periodic Review of Recommendations. We generally agree with the procedural and substantive considerations that precede the issuance of a temporary or standing recommendation. However, there is not built-in periodic review of these decisions. Even though it is likely that WHO will frequently review these recommendations and their continued necessity, and it is clear that WHO can amend or terminate these recommendations at any time, it could be useful to have an automatic sunset provision on recommendations if they are not explicitly renewed. For example, temporary recommendations could automatically expire after 30 or 60 days if WHO does not renew them. There would be no limit on renewals, so long as the public health threat persisted, but this structural effort would require WHO to periodically reassess their recommendations.

Protection of the Rights of Persons and Non-Discrimination. Another area that could be supplemented is the discussion of protections of human rights. This discussion is

¹ Gostin LO. *Public Health Law: Power, Duty, Restraint*. Berkeley: University of California Press; 2000.

found briefly in article 36(1). It may be useful to comprehensively address this issue, giving examples of the types of rights that need to be protected through the implementation of the Regulations and citing to some of the specific international documents that contain these rights (e.g., ICCPR, ICESCR, CEDAW, CRC, CERD). The specific non-discrimination provision found in article 33(1) could also be augmented to require States to actively take measures to prevent stigma and discrimination, as well as preserve privacy and confidentiality.

Informed Consent. Article 36(2), requiring informed consent before invasive treatments (e.g., medical examination, vaccination, or prophylaxis) are administered, is a good addition to the Regulations. It may be useful to further state that those who refuse consent may be barred from entry or isolated until such time as there ceases to be a reason to believe that they are carrying a dangerous disease. There is a delicate balance to be found between human rights such as bodily integrity and protection of the public's health. At present, the draft revised IHR does not seek to address that balance.

Use of Additional Public Health Measures by States. Articles 34, 35, and 36 discuss the way in which standards for taking public health measures against infectious disease are understood under the Regulations. However, it is unclear whether national governments are expected to use these standards as a floor or a ceiling. Article 34 warns States not to exceed public health measures recommended by WHO (i.e., measures that restrict international traffic more than WHO has deemed necessary). We note there is no equivalent Article that says that States should not exceed WHO recommendations by unreasonably interfering with human rights. This would be a helpful addition.

Article 35 states that WHO may ask States to either increase or decrease the scope of measures taken. Article 37 permits States to exceed WHO health standards for certain groups, but then cautions the State to not to allow for inferior standards of hygiene. In addition to the questionable practice of explicitly permitting the state to impose higher standards against specific, potentially vulnerable groups (e.g., migrants and nomads), these three articles present a somewhat confusing, even conflicting, picture of what States may do. It would be helpful to have a more simply articulated statement of whether and when the State could impose greater public health measures.

Separation of Affected and Suspect Persons. When airports, ports, and ground crossings provide facilities for isolation of affected and suspect persons, it is imperative that suspect persons are not kept in the same areas as affected persons. This avoids the potential exposure of non-infected suspect persons that can result from additional contact with affected persons. This requirement should be made clear in Annex 1(B)(2) where the capacities of these areas are outlined. The main point is to ensure the health and safety of people in isolation through, for example, adequate medical treatment and care, food, and other necessities. If the IHR spelled this out, it would be helpful.

Inclusion of Specific Yellow Fever Requirements. The change from the limited disease-specific focus of the existing IHR to the more general syndromic and risk-based model in these IHR Revisions is a positive step to address emerging threats. In spite of

this, Annex 7 outlines additional requirements for yellow fever. These additional disease-specific requirements may not be necessary.

Incentives to States. The WHO background document on the IHR Revisions (*Global Crises – Global Solutions, Managing public health emergencies of international concern through the revised International Health Regulations*, WHO/CDS/CSR/GAR/2002.4, 2002, page 3) suggests that one of the constraints on the current version of the IHR is a lack of incentives for States to comply. While the proposed IHR Revisions increase incentives somewhat to remedy this deficiency, additional incentives could be considered in light of the strong pressure on a State to not report a public health risk for fear of negative economic and reputation repercussions. The IHR Revisions in their current form present States with the ability to notify WHO confidentially and promise greater transparency in the WHO decision-making process, which may incentivize States to cooperate with the WHO. Additional incentives could include measures such as requiring the WHO to note specifically in its reports to the WHA which States have complied effectively with the Regulations or to otherwise publicly commend States with good records of public health protection. Other forms of incentive for State compliance would be helpful.

Good Governance. The WHO should become a model of good governance that all nations could emulate.² The draft revised IHR encourage a deliberative and open process by verification of data accuracy, communication with the affected countries, and public availability of reported data. Good governance should be based on the principles of fairness, objectivity, and transparency. Fairness requires that decisionmaking does not favor particular regions, countries, or power structures. International relations often favor the privileged and powerful, leaving poor nations disproportionately burdened by infectious diseases. Objectivity requires evidence-based decisionmaking. The WHO gains its moral authority through science; WHO’s judgments must be (and must be seen to be) influenced by the best available scientific evidence. Transparency requires open and accountable decisionmaking. The process for arriving at recommendations or regulatory actions should be visible and the reasons publicly explained. By incorporating the principles of fairness, objectivity, and transparency in the draft revised IHR, WHO would gain global respect and serve as a model of good governance for nations.

Additional comments and minutiae:

- Article 17 (b) states that the health authority may “require on arrival or departure inspection of conveyances, containers, cargo, goods and baggage *on arrival.*” (italics added) This doesn’t really make sense in the context, so the last two words should probably be deleted.
- The term health administration is consistently used in lower case letters, with the exception of Annex 1 (A)(1)(a) and Annex 6(1), where it is capitalized. These should be changed to be consistent with the other usages of the term.

² Fidler D. *International Law and Infectious Diseases*. Oxford: Clarendon Press; 1999.

- A slightly different standard is used for the Vaccination or Prophylaxis certificate compared to the Model of Maritime Declaration of Health and the Health Part of the Aircraft Declaration. While Annex 6(2) seems to require States to use the exact format of the Model International Certificate of Vaccination or Prophylaxis (“No departure shall be made from the model of the certificate specified in this Annex”), the standard for the other documents is less strict (the documents “shall conform with the model specified”) (See article 28(3), 29(1)).
- The discussion of the temporary recommendation process (Annex 3) reiterates that despite the advice of the Emergency Committee, the Director-General shall make the final determination on these matters. Even though the process for issuing standing recommendations (Annex 10) follows a similar process and the Review Committee has a similar advisory function, there is not an analogous statement that the Director-General shall make the final determination on these matters. Is this an intentional omission or not?
- In Annex 5 (8), the first phrase is confusing. It starts “[o]n arrival from an affected area of a conveyance”. Does this phrase refer to the arrival of a conveyance from an affected area, or to an arrival from an affected area within (i.e., inside of) a conveyance? We assume the former rather than the later, but please clarify.

Thank you for the opportunity to review the IHR Revisions. These Regulations will be a great step forward for international public health practice. We congratulate WHO for this important effort to achieve global health.