Editorial

The Revised International Health Regulations (2005): Impact on Yellow Fever Vaccination in Clinical Practice

Annelies Wilder-Smith, David R. Hill, and David O. Freedman*

Travellers’ Screening and Vaccination Clinic, Department of Medicine, National University Hospital of Singapore, Singapore; National Travel Health Network and Centre and London School of Hygiene and Tropical Medicine, London, United Kingdom; W. C. Gorgas Center for Geographic Medicine, Division of Infectious Diseases, University of Alabama at Birmingham, Birmingham, Alabama

On June 15, 2007, after a decade in the making, the revised International Health Regulations (IHR (2005)) replaced the previous IHR (1969) for all World Health Organization (WHO) member countries.1,2 The IHR provide the legal framework for preventing national public health emergencies from spreading internationally. The extent of international travel in the modern world presents an extraordinary opportunity for international disease transmission. IHR (2005) are now better adapted to the increasing volume and speed of international traffic and trade than were their predecessors.3 The revision has broadened the scope of notification of health events to WHO from three diseases (cholera, plague, and yellow fever), to “all events which may constitute public health emergencies of international concern.”4 IHR (2005) are far ranging in scope and have broad implications for national, regional, and super-governmental spheres. At the same time, from the perspective of the practicing clinician, there are some immediate practical consequences with regards to the international vaccine certificate for travelers. The extended spectrum of diseases and events under IHR (2005) that may cause a public health emergency of international concern necessitated a revision of the existing “International Certificate of Vaccination or Revaccination Against Yellow Fever” to the “International Certificate of Vaccination or Prophylaxis” (ICVP). The change in name, and a completely new format whereby the name of the vaccine or prophylaxis must be written out each time, enables the certificate to be used to document prevention and prophylaxis against international public health threats in addition to yellow fever, should they be mandated at any time by WHO. However, at the present time, yellow fever remains the only disease for which proof of vaccination may be required of travelers as a condition of entry. Vaccination against yellow fever has been required for several decades by many countries with receptive mosquito vectors to prevent the importation of this disease virus from a country that had ongoing transmission. Importation of the virus by an infected traveler could potentially lead to the establishment of infection in mosquitoes and primates, with a consequent risk of infection for the local population. Countries declaring such a requirement continue to include those with and without current yellow fever transmission themselves. No North American or European country currently requires proof of yellow fever vaccination for any arriving passenger, although receptive vectors are present in the southern portions of each of these continents.

Blank ICVP forms may be purchased directly from WHO or may be printed by national health authorities adhering strictly to the design and format specified in Annex 6 of IHR (2005) (http://www.who.int/csr/ihr/ivc_no_logo.pdf). Use of the WHO or a national logo is not a required component of the ICVP. However, the WHO logo may not be included in any form on a version of the ICVP printed or published by an organization, corporation, or entity different from WHO itself or a WHO member state. Policies on the use of national logos will vary by country. Certificates in the old format and issued prior to June 15, 2007 will remain valid for 10 years, but from June 15, 2007 onwards, the certificate should not depart from what is specified in IHR (2005). During the six-month transition period required for countries to design and print new format ICVPs, WHO has stated that “countries may consider continuing to recognize and accept certificates using the format required by the IHR (1969).”5 From December 15, 2007, member states could potentially refuse entry of travelers who arrive without the new certificate so yellow fever vaccine providers should cease use of old format certificates by that date.

In the United States, the state and territorial health departments have been delegated the responsibility of designating and supervising non-federal yellow fever vaccination centers within their jurisdictions since 1977. The “uniform stamp” issued by U.S. states is required by law to validate the ICVP and may only be issued to physicians. Nurses and other clinicians may administer yellow fever vaccine under the auspices of a licensed physician and stamp holder associated with the practice under an agreed protocol or standing order. Currently, pharmacists may administer many or most vaccines without a physician’s supervision or order in 37 states (http://www.pharmacist.com). In at least five states pharmacists may now administer yellow fever vaccine under a physician’s protocol (Division of Global Migration and Quarantine [DGMQ], Centers for Disease Control and Prevention [CDC], personal communication). The DGMQ is responsible for development and implementation of the U.S. version of the ICVP to be used nationally. Information is available from http://www.cdc.gov/travel. The DGMQ also assists states in ensuring the compliance of uniform stamp holders with all requirements for handling, storage, and administration of yellow fever vaccine.

IHR (2005) specifically confer responsibilities and obligations upon “state parties” (countries) that are signatories; it is up to each signatory country to develop their own policy and format to proceed with printing and distribution of ICVPs.
Thus, supra-national entities such as the European Union have no unique policy or implementation directives that would be applicable. In the United Kingdom, the National Travel Health Network and Center (NaTHNaC) has coordinated with the devoled health authorities the printing and distribution of the new certificate in England, Wales, Northern Ireland, and Scotland. Further information about this process and obtaining the new certificate in the United Kingdom is available from the NaTHNaC website (http://www.nathnac.org).

There have also been changes to the terminology defining yellow fever disease risk. The term “infected area” is no longer included in the IHR with respect to yellow fever or other diseases.\(^2\) The term “areas or countries with ‘risk of yellow fever transmission’” is used in IHR (2005).\(^2\) WHO operationally defines these areas on the basis of the following criteria: yellow fever infection in humans or non-human primates has been reported currently or in the past, the presence of the mosquito vector and non-human primate reservoirs.\(^6\) The term “endemic area” is also not part of IHR (2005), but has been commonly used for many years by individual countries in their stated entry requirements, in national vaccination guidelines for travelers, including those by the United States, and in maps showing yellow fever risk areas.

State parties that are signatories to IHR (2005) can declare to WHO at any time their right to require an ICVP for yellow fever from a traveler arriving from areas or countries with risk of yellow fever transmission. An important distinction is that an individual country’s requirements are not designed to protect individual travelers from a risk of yellow fever, but rather to protect the country from the introduction of yellow fever by the traveler. Each year, nine million persons from North America, Europe, and Asia travel to countries in Africa and South America where yellow fever transmission occurs; the number of travelers who actually visit regions within these countries in which yellow fever transmission occurs may exceed three million.\(^7\) For those countries with a risk of yellow fever but without a requirement for yellow fever vaccination under IHR (2005), immunization against yellow fever is still recommended. Countries that require YF vaccination and/or that have risk of yellow fever transmission are published by WHO on an annual basis in International Travel and Health (http://www.who.int/ith) and are also listed in the CDC publication Health Information for International Travel 2008 (http://wwwnc.cdc.gov/travel/content/YellowBook.aspx).

The language that deals with travelers who were merely transiting an airport in an area with risk of yellow fever transmission has changed. IHR (1969) tended to exclude these travelers from any yellow fever vaccination requirements made by the final destination country. However, in IHR (2005), this language is not found. Thus, the new IHR give countries wider latitude in applying their entry requirements to include areas where travelers had direct air transit stops. In practice, how individual countries will view these transit stops remains to be seen. As an example, Brazil, a country with legitimate concern over receptive Aedes vectors in the Sao Paulo megalopolis, has already broadened its requirements in this regard (http://www.anvisa.gov.br/divulga/noticias/2007/160207_1.htm).

IHR (2005) enable clinicians who decide that yellow fever vaccine is contraindicated on medical grounds to provide the traveler with a letter with the reasons for that opinion, which can be presented to immigration authorities upon arrival at the destination.\(^2\) Acceptance of such “waiver letters” is at the complete discretion of the destination country. On arrival, the receiving country may also quarantine the traveler for up to six days, or request that the traveler be placed under surveillance. Except for the presence of a clinician’s signature, no specific format for written documentation of medical contraindication is specified by IHR (2005). However, IHR (2005) explicitly state that the clinician must warn the unvaccinated traveler of the potential risk of yellow fever at the destination.

The changes mandated by IHR (2005) present an opportunity for state parties to review their programs for oversight and certification of practices administering yellow fever vaccine. These changes are a requirement of IHR (2005) and have recently been highlighted as an important way to improve the standard of pre-travel health care of travelers.\(^2\)^\(^8\)

The implementation of IHR (2005) is an important step forward in the coordinated global response to public health events. As a first step, introduction of the new “International Certificate of Vaccination or Prophylaxis” will test the readiness of clinicians and public health authorities to adopt these new regulations.

Received December 3, 2007. Accepted for publication January 4, 2008.

Authors’ addresses: Annelies Wilder-Smith, Travellers’ Screening and Vaccination Clinic, Department of Medicine, National University of Singapore, 5 Lower Kent Ridge Road, Singapore 119074, Telephone: 65-6779-1490, Fax: 65-6779-1489, E-mail: epwvs@pacific.net.sg. David R. Hill, National Travel Health Network and Centre and London School of Hygiene and Tropical Medicine, Hospital for Tropical Diseases, Mortimer Market Centre, Capper Street, London WC1E 6JH, United Kingdom, Telephone 44-845-155-5000 extension 5943, Fax: 44-20-7380-9486, E-mail: david.hill@uclh.org. David O. Freedman, W. C. Gorgas Center for Geographic Medicine, Division of Infectious Diseases, University of Alabama at Birmingham, 1530 3rd Avenue South, BBRB 203, Birmingham, AL 35294-2170, Telephone: 205-934-1630, Fax: 205-934-5600, E-mail: freedman@uab.edu.

REFERENCES