

**COMMITTEE OF EXPERTS ON THE TRANSPORT
OF DANGEROUS GOODS AND ON THE GLOBALLY
HARMONIZED SYSTEM OF CLASSIFICATION AND
LABELLING OF CHEMICALS**

Sub-Committee of Experts on the

Transport of Dangerous Goods

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Transport of Infectious Substances

Transmitted by the World Health Organization

Introduction

In the past few months the world has changed. Dramatically.

It is evident since the events of September 2001, that there must be global preparations for the possibility that people are deliberately harmed with biological agents. Now more than ever, countries need to strengthen their capacity to respond to the consequences of both natural and deliberate incidents of disease outbreak. The World Health Organization (WHO) is ready to assist countries if they should experience the release of a biological agent. Indeed, natural epidemics and those due to the intentional release of biological agents both present in a similar manner.

WHO's "Global Outbreak Alert and Response Network" can quickly detect and respond to outbreaks of communicable disease, whether natural or deliberate. This global network works under the framework of the *International Health Regulations*, the legal instrument which governs the reporting of epidemic-prone diseases and the application of measures to prevent their spread. In daily contact with its 191 Member States and other partners, WHO systematically collects information, and is committed to its rapid verification and the coordination of the international response, if required. Each year, about 200 outbreaks of potential international importance are actively verified, involving virtually all countries.

The confirmation of diagnoses usually requires accurate and urgent analyses, which frequently can only be performed at laboratories that have the technical capacity to detect a wide variety of etiological agents. Not every country has such capacity, requiring transport of samples for initial or confirmatory analysis beyond their national boundaries.

Accordingly, comprehensive international shipping regulations need to be put in place to assure the timely, effective and efficient transport of such samples to destination. Delays of diagnoses due to difficulties in transport would pose serious problems for the control of epidemics.

In this perspective, WHO organized the "WHO Biosafety and Transport*" meeting on 8-10 October in Lyon to revise the current UN Model Regulations.

Forty-eight experts in biosafety, communicable diseases, medical outcomes, epidemiology and waste management gathered to examine the entire question of transport biosafety. Among scientific experts, WHO welcomed the participation of the Chairman of the UNCTEDG, Transport Canada, UPU and other transport representatives.

At the meeting it was acknowledged that the current system that regulates the transport of infectious substances and diagnostic specimens is not satisfactory. The existing division 6.2 of the *UN Recommendations on the Transport of Dangerous Goods - Model Regulations* for the transport of infectious substances needs revision for clarity, completeness and ease of use. It must not create

public health issues and economic burdens through difficulties encountered in its practical application. The following are examples of areas needing revision:

- 1.1 The current definitions in "2.6.3 Division 6.2 - Infectious substances" cause confusion and allow personal interpretation. For example, in the current text, the shipper must make a subjective judgement on the content of a sample and decide which containment device is required.
- 1.2 Although risk groups were never intended for use in transport regulations, classification according to WHO risk groups is still included in the definitions of infectious substances and biological products. This classification system does not adequately differentiate between "infectious" and "diagnostic" samples, as stated in UN/CETDG/21/INF.51.
- 1.3 Samples "packed and marked in accordance with PI650 are not subject to any other requirements in the Model Regulations". However, the UN number assigned to these automatically defines them as dangerous goods. The UN number can be interpreted as implying that the shipper is required to be trained. However, there is currently no specification of what the training should cover, how long the training should be, and how often it should be repeated. Likewise, training certification and training records should be defined.
- 1.4 Current regulations are not harmonized with other international biosafety conventions (Basel Convention on transboundary movement of medical waste, Convention on Biological Diversity Cartagena Protocol on Biosafety). These conventions refer to the UN Model Regulations as regulatory instruments associated with their own remit.

In conclusion the current regulations do not address in the most appropriate way the needs of modern disease and outbreak investigations. WHO will prepare a revision.

Upon consultation with the international panel of expert advisors, some provisional consensus was reached on the following points:

WHO recommendations (global consensus pending)

- 2.1 The title "2.6.3 Division 6.2 - Infectious substances" in the *UN Recommendations on the Transport of Dangerous Goods - Model Regulations, 12th edition*, is currently being discussed to be changed to "2.6.3 Division 6.2 - Biohazardous substances". As opposed to "infectious", the term "biohazardous" is comprehensive of all categories described in the recommendations for modifications applying to division 6.2 described in the points listed below.
- 2.2 The concept of "Universal Precautions" (UP), expanded for clarity in the Appendix attached to this INF document, was considered applicable for transport regulations. According to UP, blood and certain body fluids of ALL patients are considered potentially infectious. Consequently, no definition in the regulatory text should include phrases like "reasonably expected to contain" or "believed to contain" any more.
- 2.3 It was agreed that the risk of exposure to a "biohazardous substance" during transport is minimized with the use of the packaging suggested under point 4.
- 2.4 The group evaluated the performances and requirements of the existing packing instructions (PI) 620 and 650. Altogether, the concept of the triple packaging system was deemed appropriate for transport purposes. It was agreed that a 620-like PI would be sufficient and satisfactory for transporting "biohazardous substances" included in category A (defined under points 5 and 6), and that a 650-like PI would be adequate for the transport of all other "biohazardous substances", included in category B (defined under point 5).
- 2.5 The classification of samples within the two PIs was discussed, and it was tentatively decided that: (a) "biohazardous" pathogens included in category A should be transported according to a modified PI620 with full documentation, and that (b) "biohazardous"

materials not falling into category A would by default be shipped following a modified PI650.

- 2.6 The group prepared the initial draft list of "biohazardous" pathogens to be included in category A. The draft is currently being finalized.
- 2.7 When there is inadequate data to identify "biohazardous substances" belonging to category A, but clinical symptoms suggest the presence of such agents (e.g. during outbreak investigations), the use of a 620-like PI was deemed appropriate. The required specification on the shipper's declaration may in these cases refer to "outbreak/disease investigation".
- 2.8 It was not deemed appropriate to keep UN 3373 for "diagnostic specimens", since the category was changed to be included in category B. With reference to the problem outlined in point 1.3 of the above introduction, the use of UN 3373 for category B is currently still questioned.
- 2.9 The UN numbers UN 2900 and UN 2814 were discussed, and the classification of samples as UN 2814 or UN 2900 is currently still being debated. In fact, some "biohazardous" agents included in category A may require both identification numbers, creating unnecessary confusion. Careful formulation of the definitions for UN 2900 and UN 2814 is still required.
- 2.10 For easy and direct recognition of boxes, the addition of a particular symbol (e.g. caduceus) on the surface of PI650-like packages was discussed.
- 2.11 The possibility of adding decontamination instructions and an emergency contact number on the outside of PI650 packages was discussed, but no consensus was reached.
- 2.12 References to "WHO Risk Groups", as originally described in the *WHO Laboratory Biosafety Manual*, were eliminated from all definitions.
- 2.13 Blood for transfusion, organs for transplant and biological materials (as defined in the current *UN Recommendations on the Transport of Dangerous Goods - Model Regulations, 12th edition*) that are currently exempted from the regulations should stay exempted.

Conclusions

Following the discussions at the "WHO Biosafety and Transport" meeting in Lyon and the results of further consultations thereafter, WHO is in the process of finalizing a proposal for amendments to the *UN Recommendations on the Transport of Dangerous Goods - Model Regulations, 12th edition*.

The document is planned to be submitted for consideration at the 21st meeting of the UNSCETDG, in July 2002.

Statement

This INF document was developed at WHO with the help of "WHO Biosafety and Transport" meeting participants.

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Appendix to UN/SCETDG/20/INF.41

Universal Precautions for Prevention of Transmission of HIV and other Bloodborne Infections

(source: <http://www.cdc.gov/ncidod/HIP/blood/universa.htm>)

“Universal Precautions,” as defined by the Centers for Disease Control and Prevention (CDC), are a set of precautions designed to prevent transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens when providing first aid or health care. Under universal precautions, **blood and certain body fluids of all patients are considered potentially infectious** for HIV, HBV and other bloodborne pathogens.

Universal precautions took the place of and eliminated the need for the isolation category "Blood and Body Fluid Precautions" in the 1983 CDC Guidelines for Isolation Precautions in Hospitals. However, implementing universal precautions does not eliminate the need for other isolation precautions, such as droplet precautions for influenza, airborne isolation for pulmonary tuberculosis, or contact isolation for methicillin-resistant *Staphylococcus aureus*.

Universal precautions differ from the system of Body Substance Isolation (BSI) used in some institutions. For information about BSI, refer to the following articles:

1. Lynch P, et al. Rethinking the role of isolation precautions in the prevention of nosocomial infections. *Annals of Internal Medicine* 1987;107:243-246.
2. Lynch P, et al. Implementing and evaluating a system of generic infection precautions: Body substance isolation. *American Journal of Infection Control* 1990;18:1-12.

In 1996, CDC published new guidelines (standard precautions) for isolation precautions in hospitals. Standard precautions synthesize the major features of BSI and universal precautions to prevent transmission of a variety of organisms. Standard precautions were developed for use in hospitals and may not necessarily be indicated in other settings where universal precautions are used, such as child care settings and schools.

Universal precautions apply to blood, other body fluids containing visible blood, semen, and vaginal secretions. Universal precautions also apply to tissues and to the following fluids: cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids. Universal precautions do not apply to feces, nasal secretions, sputum, sweat, tears, urine, and vomitus unless they contain visible blood. Universal precautions do not apply to saliva except when visibly contaminated with blood or in the dental setting where blood contamination of saliva is predictable.

Universal precautions involve the use of protective barriers such as gloves, gowns, aprons, masks, or protective eyewear, which can reduce the risk of exposure of the health care worker's skin or mucous membranes to potentially infective materials. In addition, under universal precautions, it is recommended that all health care workers take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices.

Pregnant health care workers are not known to be at greater risk of contracting HIV infection than are health care workers who are not pregnant; however, if a health care worker develops HIV infection during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health care workers should be especially familiar with, and strictly adhere to, precautions to minimize the risk of HIV transmission.

WRITTEN GUIDELINES: UNIVERSAL PRECAUTIONS

Universal precautions are discussed in the following documents:

1. [CDC. Recommendations for prevention of HIV transmission in health-care settings.](#) MMWR 1987;36(suppl no. 2S).
2. [CDC. Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings.](#) MMWR 1988;37:377-388.
3. [CDC. Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers.](#) MMWR 1989;38(S-6):1-36.

These three documents may be obtained by calling the AIDS Hotline at 1-800-342-2437 or the National AIDS Information Clearinghouse at 1-800-458-5231.

In addition, the Occupational Safety and Health Administration (OSHA) has published a standard on "bloodborne pathogens." For information about this document, call 202-219-7157.

For information on infection control in dental practice, call 1-800-458-5231 to obtain "The Infection Control File." For further questions on dental practice, call the Division of Oral Health, CDC, telephone 770-488-3034.

GLOVING, GOWNING, MASKING, AND OTHER PROTECTIVE BARRIERS AS PART OF UNIVERSAL PRECAUTIONS

All health care workers should routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure during contact with any patient's blood or body fluids that require universal precautions.

Recommendations for the use of gloves are presented in detail in the Morbidity and Mortality Weekly Report dated June 24, 1988, which is available by calling the National AIDS Information Hotline at 1-800-342-2437 or the National AIDS Information Clearinghouse at 1-800-458-5231.

Gloves should be worn:

- for touching blood and body fluids requiring universal precautions, mucous membranes, or nonintact skin of all patients, and
- for handling items or surfaces soiled with blood or body fluids to which universal precautions apply.

Gloves should be changed after contact with each patient. Hands and other skin surfaces should be washed immediately or as soon as patient safety permits if contaminated with blood or body fluids requiring universal precautions. Hands should be washed immediately after gloves are removed. Gloves should reduce the incidence of blood contamination of hands during phlebotomy, but they cannot prevent penetrating injuries caused by needles or other sharp instruments. Institutions that judge routine gloving for all phlebotomies is not necessary should periodically reevaluate their policy. Gloves should always be available to health care workers who wish to use them for phlebotomy. In addition, the following general guidelines apply:

1. Use gloves for performing phlebotomy when the health care worker has cuts, scratches, or other breaks in his/her skin.
2. Use gloves in situations where the health care worker judges that hand contamination with blood may occur, e.g., when performing phlebotomy on an uncooperative patient.
3. Use gloves for performing finger and/or heel sticks on infants and children.
4. Use gloves when persons are receiving training in phlebotomy.

The Center for Devices and Radiological Health, Food and Drug Administration (FDA), has responsibility for regulating the medical glove industry. For more information about selection of gloves, call FDA at 301-443-8913.

Masks and protective eyewear or face shields should be worn by health care workers to prevent exposure of mucous membranes of the mouth, nose, and eyes during procedures that are likely to generate droplets of blood or body fluids requiring universal precautions. Gowns or aprons should be worn during procedures that are likely to generate splashes of blood or body fluids requiring universal precautions.

All health care workers should take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices during procedures; when cleaning used instruments; during disposal of used needles; and when handling sharp instruments after procedures. To prevent needlestick injuries, needles should not be recapped by hand, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. After they are used, disposable syringes and needles, scalpel blades, and other sharp items should be placed in puncture-resistant containers for disposal. The puncture-resistant containers should be located as close as practical to the use area. All reusable needles should be placed in a puncture-resistant container for transport to the reprocessing area.

General infection control practices should further minimize the already minute risk for salivary transmission of HIV. These infection control practices include the use of gloves for digital examination of mucous membranes and endotracheal suctioning, handwashing after exposure to saliva, and minimizing the need for emergency mouth-to-mouth resuscitation by making mouthpieces and other ventilation devices available for use in areas where the need for resuscitation is predictable.

Although universal precautions do not apply to human breast milk, gloves may be worn by health care workers in situations where exposures to breast milk might be frequent, e.g., in breast milk banking.

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URL: <http://www.cdc.gov/ncidod/HIP/blood/universa.htm>