

Recommendations From the National AIDS Plan Committee (SPNS), National AIDS Study Group (GESIDA), the Center for Epidemiological Studies on Sexually Transmitted Infections and AIDS in Catalonia (CEEISCAT), the Spanish Society of Pediatric Infections (SEIP), and the Spanish Society of Pediatrics (AEP) on Postexposure Prophylaxis Against HIV, HBV, and HCV in Adults and Children

Objective: To facilitate appropriate use of prophylaxis after occupational and nonoccupational exposure to HIV, HBV, and HCV, by providing current updated evidence-based scientific information.

Methods: The recommendations were drawn up and agreed upon by an expert panel from the SPNS and Scientific Societies, after an exhaustive review of the latest relevant epidemiological and clinical studies that have been published in the medical literature and/or presented at congresses and scientific forums.

Results: The risk of transmission of HIV, HBV and HCV after occupational exposure depends on the nature of the exposure, the serological status of the health professional, the virological status of the “source patient” and the time from exposure. Postexposure prophylaxis will be always recommended in cases of high and very high risk and it will be offered for other risk situations. Ideally, prophylaxis should start during the first 6 hours but it must be administered no later than 72 hours after exposure. In general, a combination of 3 antiretrovirals drugs should be used, except in low-risk situations, where 2 antiretrovirals would be acceptable. Follow-up should last 24 weeks. In nonoccupational exposure, the patient will be evaluated according to the risk level after exposure and the necessary action will be taken. Consensus must always be sought between doctor and patient. Prophylaxis will always be recommended for high-risk exposure, and will be considered when risk is appreciable. For non-occupational exposure, prophylaxis will be provided once the exceptional exposure is confirmed. The regimen will be the same as for occupational exposure.

Conclusions: The decision to start a postexposure prophylaxis is directly related to final risk classification. Ideally, it should be started within 6 hours and must be administered no later than 72 hours after exposure. A 3-drug regimen should be used. Risk classification tools and action protocols should be available in health care facilities that dispense antiretroviral drugs.

Key words: Postexposure prophylaxis. Occupational exposure. Nonoccupational exposure. HIV.

Introduction

This text is a summary of the Consensus Paper on recommendations for prophylaxis after occupational and non occupational exposure to HIV, HCV, and HCV. Its main objective is to facilitate appropriate use of postexposure prophylaxis (available from www.msc.es and www.gesida.seimc.org). The recommendations drawn up by the members of the National AIDS Plan Committee (SPNS) and panel of experts from the Spanish AIDS Study Group (GESIDA), the Spanish Association of Pediatrics (AEP), and the Center for Epidemiological Studies on Sexually Transmitted Infections and AIDS in Catalonia (CEEISCAT) include the evaluation of the risk of postexposure transmission, indications for starting prophylaxis and drug regimens, follow-up of exposed individuals, and special situations. During the preparation of the document, existing scientific evidence was updated^{1,2} and the following levels of evidence were used based on the type of study analyzed: Level A, randomized and comparative studies; Level B, cohort studies or case-control studies; and Level C, descriptive studies or expert opinions.

Occupational exposure occurs when a health professional at work is exposed to blood, tissue, or fluids that may be contaminated with HIV, HBV, or HCV, as the result of a percutaneous lesion affecting the skin or mucous membranes.

Nonoccupational exposure occurs when an individual is exposed to fluids that may be contaminated by HIV, HBV, or HCV, outside work or perinatal settings.

Measures to be Taken in the Case of Exposure to HIV

As a general rule, and regardless of whether the exposure is occupational or not, *primary prevention* is aimed at preventing exposure. In the case of occupational exposure to HIV, preventing exposure includes measures that must be developed in healthcare institutions. These include education and training of staff in universal precautions, availability and use of barrier materials and containers for potentially contaminated material, 24-hour guarantee of advice and care, availability of a diagnosis based on serology testing within a maximum of 2 hours, timely access to medication when necessary, follow-up protocols, availability of and access to health professionals responsible for care and follow-up, and centralized notification criteria. In the case of

nonoccupational exposure to HIV, health education at both public and individual level must explain how to prevent or reduce the possibility of exposure.

Local preventive measures are valid for both types of exposure and can be applied immediately (Table 1).

Treatment schedules include the choice of antiretroviral drugs, regimens, and duration of treatment. Current guidelines take into consideration the risk of the different types of exposure, knowledge and experience in the field of antiretroviral therapy, and available data on toxicity.^{1,3,4,5,6} Recommendations on the selection of antiretroviral drugs in postexposure prophylaxis have followed the patterns of use of these drugs and are based on the opinion of experts (Level C). Possible regimens of choice and alternatives are presented in Table 2. As a general rule, and wherever possible, a physician with broad experience in antiretroviral therapy will evaluate the patient and choose the regimen. This is obligatory in situations of moderate to high risk.

In general, if resistance is suspected or confirmed in the source patient, the regimen chosen will be the postexposure regimen that would normally be chosen as a rescue strategy. In pregnant women, the choice will take into account the possible adverse effects and the specific risks of some antiretroviral drugs that are contraindicated during pregnancy. The broadest experience in pregnant women is with zidovudine, lamivudine, nelfinavir, and lopinavir-ritonavir.

OCCUPATIONAL TRANSMISSION OF HIV, HBV, AND HCV

There are several differences between the transmission of HIV, HBV, and HCV in occupational exposure. In occupational exposure, HCV is not transmitted efficiently to blood, it is rarely transmitted via exposure of the mucous membranes to blood, and there have been no reports of transmission via broken skin. The mean incidence of seroconversion after percutaneous exposure with a positive HCV-infected source is 1.8% (0-7%).^{7,8,9,10} In the case of occupational exposure to HBV, the risk depends on the intensity and type of contact with the blood. The mean risk of transmission of HIV after percutaneous exposure has been calculated to be 0.3% (95% CI, 0.2%-0.5%)¹¹ and after mucosal exposure it is 0.09% (95% CI, 0.006%-0.5%). Transmission via broken skin and other fluids or tissue has been measured insufficiently or not at all.

1. Evaluation of the Risk of Transmission of HIV, HBV, and HCV

The risk of transmission of HIV depends on the type of exposure, the time from the exposure, virologic status of the source, and the serologic situation of the professional. There is a direct relationship between the magnitude of the accident (volume of blood and viral load) and the possibility of seroconversion. The existence of low or undetectable viral loads does not rule out the risk of infection, given that the viral load in plasma measures extracellular viral particles in peripheral blood, but does not evaluate the existence of infected cells with the ability to infect.

Factors associated with the accident include the depth of penetration, the type of material used, barriers in place, unbroken skin or mucous membranes, and the type of fluid to which the professional has been exposed. The risk is greater when blood is visible on the device.

If the serologic status of the source is unknown, a complete serology study should be made (after informed consent is obtained) as quickly as possible, and should include the option of a rapid test that provides results within 2 hours. If the serologic status is unknown, it is best to act as if the professional had been infected by HIV.

In the case of a known HIV-positive source, the immunological and virological status will be ascertained (viral load, CD4 count, previous antiretroviral therapy, and complete history of pharmacotherapy). It is important to remember that the risk is greater when the source case is a patient undergoing seroconversion or a patient in the advanced phase.

The serologic status of the exposed health professional must be ascertained by carrying out the necessary postexposure tests.

The general recommendations for occupational postexposure prophylaxis against HIV are shown in Table 3.

The risk of transmission of HBV or HCV also depends on the type of exposure, the source patient, and the person exposed. The evaluation of mode and type of exposure will be the same as for HIV. If the serologic status of the source is unknown, tests will be performed as quickly as possible after informed consent has been obtained and all procedures should be carried out as if the source was infected. The exposed professional will be considered susceptible to infection by HBV when HBsAg and anti-HBc are negative and anti-HBs are < 10 mIU/mL. If the HBV vaccination schedule is correct, follow-up will only involve a serology study at baseline and at 6 months. No efficient measures are currently available for exposure to HCV.

The proposed informed consent document, which is available in full from www.msc.es, covers risk exposures to occupational transmission of HIV, possible benefits of postexposure prophylaxis and its indications, regimens, timing, and duration, the risk and effects of antiretroviral drugs, and relevant general and specific guidelines. The model for statements and signatures is shown in Figure 1.

Recommendations

- The risk of infection after exposure depends on the characteristics of the source patient, the type of exposure, and the serologic status of the exposed individual (Level B).
- The risk is highest when the exposure involves deep penetration with a hollow needle that has been contaminated after previous venous access (artery or vein) in an HIV-infected patient with advanced disease (Level C).
- The HIV status of the exposed person and the source case must be ascertained (Level C).
- The professional should be evaluated as quickly as possible (first 2 hours after exposure) (Level C).
- Twenty-four hour advice and assistance must be guaranteed, with the availability of a serology test within 2 hours and access to medication when necessary within the established time periods (Level C).

2. Prophylaxis After Occupational Exposure to HIV

The general recommendations presented in Table 3 should be followed. Prophylaxis should be initiated as quickly as possible, ideally within 6 hours of the incident and no later than 72 hours after the incident. The recommended duration is 28 days. Psychological support and help with symptom control should be provided. States of anxiety and stress may develop. In these cases, the clinician should provide all the necessary detailed information, including side effects and the strategies to be applied should these appear. Contact should be made easy. The patient's emotional status should be examined and, if necessary, the patient should be referred to mental health specialists.

Figure 2 shows the algorithm for occupational exposure to biological material.

The conditions that a case of occupational exposure must fulfill before postexposure prophylaxis can be considered are as follows:

- a) The source patient must be HIV-infected or have an unknown infection status with risk factors such as being an intravenous drug user (IVDU) or member of a group with a high prevalence of HIV. Prophylaxis will be interrupted if the serology test result of the source is negative.
- b) Exposure is percutaneous (needlestick, cut), mucosal, or cutaneous with broken skin (dermatitis, abrasions, wounds).
- c) The time after exposure is under 72 hours.

Recommendations for Prophylaxis After Occupational Exposure

The decision to use prophylaxis after occupational exposure depends on the type of exposure and on the clinical and virological status of the source patient. The following conditions must be met.

- As a general rule, a 3-drug regimen (2 NRTIs + 1 PI) is recommended, except in situations of very low risk, in which case a 2-drug regimen would be acceptable (2 NRTIs) (Level C).
- Independently of the source patient's clinical and virological status, a 3-drug regimen is mandatory in all high-risk exposures (Level C).
- When the risk is intermediate and the source patient has noncontrolled HIV infection (>50 copies/mL, symptomatic, or with primary infection), a 3-drug regimen is recommended. In exposure to a source patient with controlled HIV infection (viral load <50 copies/mL, asymptomatic), a 2-drug regimen is acceptable (Level C).
- If the source patient's serology results are unknown or pending, postexposure prophylaxis should be chosen on an individual basis. When the probability is reasonable and the risk exposure is intermediate or high, it is better to start prophylaxis and later re-evaluate the situation (Level C).

Follow-up should be for a minimum of 24 weeks. Some authors recommend a checkup at 12 months due to the possibility of late seroconversions.

NONOCCUPATIONAL TRANSMISSION OF HIV, HBV, AND HCV

A calculation of the risk of transmission depends on the prevalence of HIV in the population to which the source belongs and on the estimated risk of exposure. The risk of transmission of HIV is presented in Table 4.

Figure 3 shows the algorithm for nonoccupational exposure to biological material.

1. Evaluation of Risk in Nonoccupational Exposure

The probability of HIV transmission depends on the type of exposure, the virologic status of the source patient, and additional factors^{1,12,13} such as sexual attack (rape), source infectivity, presence of other sexually transmitted diseases (STD), genital lesions or wounds, and bleeding or menstruation.

The type of exposure includes sexual (consensual), rape, transfusion of blood or blood derivatives, accidents with needles or sharp objects, contact with fluid or infected tissue, bites, and transmission during labor and breastfeeding. In practice, nonoccupational transmission of HIV almost always occurs parenterally or through sexual contact. Evaluation according to risk practice differentiates the types of exposure.

The evaluation of risk of infection by sexual transmission,^{1,12,13} whether the source patient's HIV status is known or not, is shown in Table 5.

The evaluation of risk by parenteral transmission⁵⁻⁷ includes the possibility of HIV infection by the source, given the high prevalence of HIV among IVUDs in Spain. The levels of risk are shown in Table 6.

Risk of Transmission of HBV, HCV, and Other Infections

Given that HIV shares routes of transmission with HBV and HCV, in all cases it will be necessary to evaluate and carry out serology testing, vaccinate, or administer anti-HBV immunoglobulin as necessary. When exposure is by sexual contact, other STDs must always be evaluated^{1,12,13} and single-dose antibiotic prophylaxis active against *Chlamydia*, syphilis, gonococcus, and *Trichomonas vaginalis* must be administered.

2. Prophylaxis After Nonoccupational Exposure to HIV

Initially, and after the risk of transmission has been evaluated, the exceptional nature of the exposure will be confirmed, since postexposure prophylaxis should not be administered in cases of repeated exposure. In nonoccupational exposure, it is important to insist on primary prevention measures (avoidance of risk practices, correct use of barrier methods, and not sharing injecting material). Similarly, as much information as possible should be collected on the source patient and serologic follow-up of the

exposed individual should be carried out. Furthermore, the existence of other STDs should be evaluated and the relevant measures taken. The patient should be vaccinated against HBV and/or tetanus where necessary.

The conditions that nonoccupational exposure must fulfill before postexposure prophylaxis can be administered are as follows:

- a) The source patient must be HIV-infected or have risk factors in the case of an unknown infection status, ie, he or she is an IVDU or member of groups with a high prevalence of HIV (prophylaxis is stopped if the serology test results are negative).
- b) In cases of high-risk exposure (unprotected receptive anal intercourse with ejaculation, exchange of needles or syringes immediately after use) prophylaxis must be recommended, and in cases of appreciable risk (unprotected receptive vaginal intercourse, unprotected receptive anal intercourse without ejaculation, unprotected vaginal or anal insertive intercourse, unprotected receptive oral-genital intercourse with ejaculation), prophylaxis must be considered, especially if the source patient has “noncontrolled” infection
- c) The time after exposure is under 72 hours.

The general recommendations for nonoccupational postexposure prophylaxis are as follows:

- It should form part of an integrated medical intervention that includes individualized health education and clinical follow-up of the exposed person.
- The decision to start nonoccupational postexposure prophylaxis must be on an individual basis and should be agreed by the physician and the person exposed.
- Nonoccupational postexposure prophylaxis is only indicated for sporadic and unusual exposures.
- It should be started as quickly as possible, ideally within 6 hours of the risk practice, as prophylaxis is less likely to be successful the longer the period between exposure and administration.¹⁴
- Cases that are not candidates for nonoccupational postexposure prophylaxis will be advised on how to avoid new risk exposures and offered clinical follow-up.
- Before prophylaxis is started and assuming that they do not imply a delay, the following procedures must be carried out: serology testing (ELISA) and measurement of viral load, complete blood count, biochemistry, HBV and HCV

serology testing, diagnostic tests for other STDs, and a pregnancy test for all women with sexual exposure.

- Before prophylaxis is started, the individual must sign the informed consent (Figure 4).
- All individuals will be informed about the symptoms of HIV primary infection (acute retroviral syndrome) and will be directed to the appropriate clinic if necessary.

Recommendations for Nonoccupational Postexposure Prophylaxis

The decision to use nonoccupational postexposure prophylaxis depends on the type of exposure and the clinical and virologic status of the source patient. The following conditions must be met.

- Nonoccupational postexposure prophylaxis is only recommended after exposures with a considerable risk of transmission of HIV—unprotected receptive anal intercourse with ejaculation (0.5-3%) or exchanging syringes with an infected patient (0.67%)—although it can also be considered for exposures with an appreciable risk when the source has noncontrolled HIV infection (Level C).
- Antiretroviral regimens are the same as for occupational exposure. When nonoccupational postexposure prophylaxis is indicated, it is generally administered with 3 drugs (Level C)

Recommendations for Antiretroviral Therapy

- Postexposure prophylaxis will be recommended when the source has known HIV infection and there is an appreciable risk of transmission. Prophylaxis should be started within 6 hours of the contact and no later than 72 hours after the exposure. The exposed person must be able and willing to fulfill the requirements of follow-up (Level B). Nevertheless, prophylaxis could be considered after this time limit in specific cases with a high risk of transmission. Wherever possible, information will be obtained about the antiretroviral history of the source case and his/her most recent viral load determination. If the source case gives his/her consent and the results are available quickly, viral load should be redetermined and genotyping should be used to establish resistance.

- If the risk of transmission is low or it is unknown whether the source case is HIV-infected and it is not possible to carry out rapid serology testing to detect the virus, the decision to start postexposure prophylaxis will be taken by the physician and the exposed person after weighing up the potential risks and benefits in each particular case (Level C).
- If the HIV status of the source case is not known, but he/she is an IVDU or a member of a population with a prevalence of infection greater than or equal to 10%, it will be necessary to proceed as if the person was HIV-infected (Level C).
- Regardless of the serologic status of the source case, and of the considerations set out above, postexposure prophylaxis is not recommended when the risk of transmission is minimum or nonexistent (Level C).

Psychological aspects must be evaluated and the relevant action taken.

Two weeks after prophylaxis is started, follow-up should include a complete blood count and plasma biochemistry. Regardless of when postexposure prophylaxis is started, the following recommendations are proposed.

- At 4-6 weeks: complete blood count, biochemistry, and serology testing for HIV, HBV, and HCV
- At 3 months: serology testing for HIV, HBV, and HCV
- At 6 months: serology testing for HIV, HBV, and HCV

The results should indicate the appropriate action to take.

Special Situations

Pregnancy: Always examine the most recent recommendations and updates.

Sexual attack: There is a greater risk of infection and the recommendation of postexposure prophylaxis is a medicolegal procedure.

Children and adolescents: The exposure situations that can affect this group include the following: accidental needlestick with needles from HIV-infected IVDU (most common); domestic accident with a sharp object involving an infected person; other childhood accidents; sexual abuse that, although less common, involves a greater risk of transmission of the virus in children;¹⁵ and consensual sex.

The risk of transmission of HIV varies with the type of exposure, type of fluid or material, and serologic status of the source (Tables 7 and 8).

Regimens for Children and Adolescents

The obvious choice for health care in these cases will be hospital emergency departments, which should have the pediatric formulations of the medication in sufficient quantities for at least 3 days of treatment. Referral to the specialist clinic should be preferential.

a) Local measures:

- Washing the wound, skin abrasion, or mucous membranes with soap and water
- Surgical care in the case of anal and vaginal tears or wounds requiring suture

b) Data collection: questions aimed at the source and vaccination status of the child or adolescent.

- When and how the contact came about
- Is the source known? If so:
 - o Is the source receiving ARV? If so: current and past medication
 - o Is the viral load known?
- If the HIV status is unknown, are there risk factors?
- Vaccination status of child or adolescent: has the patient been correctly vaccinated against tetanus and hepatitis B?

c) Measures aimed at reducing the risk of coinfection by other agents:

- Evaluate antitetanus immunoglobulin and/or booster vaccination
- Evaluate anti-hepatitis B immunoglobulin
- Evaluate the need for antibiotics to prevent local infections and STDs
- No data are available on the use of interferon to prevent hepatitis C.

Postexposure prophylaxis is not effective in 100% of cases, and there have been reports of failure^{16,17}; therefore, the patient must be informed of this possibility and instructed how to recognize the acute viral syndrome. Adolescents should be advised about preventive measures aimed at avoiding unprotected sexual relations. Highly active antiretroviral therapy (HAART) should be started as quickly as possible, ideally during the first 6 hours and for a period of 28 days.

Recommendations

- Triple therapy including 2 NRTIs + 1 PI The recommended combination is lopinavir/ritonavir + lamivudine + zidovudine (Level C) due to the availability of pediatric formulations, experience of use, potency, and generalized availability in most centers.

- In some circumstances, it may be necessary to modify this regimen due to the onset of adverse effects, or rejection of triple therapy by the patient or guardian. The regimen may also be modified to ensure adherence if this is expected to be poor; in this case consider dual therapy with 2 NRTIs, preferably 3TC+AZT (Level C)

Although adverse effects are uncommon,^{18,19,20} toxicity may appear in up to 76% of cases¹⁸ and above in the case of triple therapy,¹⁸ and this could weaken adherence.

Table 1. Recommendations for Immediate Action in Cases of Occupational Exposure to HIV, HBV, or HCV

Percutaneous exposure ^a	Bleeding and washing with soap and water
Cutaneous contamination ^a	Washing with soap and water
Mucosal contamination ^a	Washing with water
Eyes	Rinse with clean water, saline solution, sterile water, or povidone iodine, 10%
Topical products such as chlorhexidine gluconate and/or povidone iodine can be used due to their possible antiviral effect against HBV and HCV	
Caustic agents (bleach, skin disinfectants) and aggressive maneuvers are not recommended	

^a These recommendations are equally valid for nonoccupational exposures

Table 2. Recommended Antiretroviral Drug Regimens in Cases of Postexposure Prophylaxis

	1 drug from column A + 1 drug from column B ± 1 drug from column C^a		
	A	B	C
Regimen of choice	<ul style="list-style-type: none"> • Zidovudine (AZT)^b 250-300 mg/12 h • Tenofovir^c 245 mg/24 h 	<ul style="list-style-type: none"> • Lamivudine (3TC)^b 300 mg/24 h • Emtricitabine^c (FTC) 200 mg/24 h 	<ul style="list-style-type: none"> • Lopinavir-ritonavir (coformulated) 400/100 mg /12 h
Alternative regimens	<ul style="list-style-type: none"> - Didanosine (ddl) 250-400 mg/24 h - Stavudine (d4T) 30 mg/12 h 		<ul style="list-style-type: none"> - Fosamprenavir 700 mg / 12 h + ritonavir 100 mg/12 h - Saquinavir 1000 mg/12 h + ritonavir 100 mg/12 h - Atazanavir 300 mg/24 h + ritonavir 100 mg/24 h - Nelfinavir^d 1250 mg/12 h - Efavirenz^e 600 mg/24 h

^a Recommended initial regimen in most cases of exposure is a combination of 3 drugs. ^b AZT and 3TC are commercially available as coformulations (300 mg of AZT and 150 mg of 3TC). ^c Tenofovir and emtricitabine are commercially available as coformulations (245 mg of tenofovir and 200 mg of emtricitabine). ^d Temporarily withdrawn from the market due to contamination during the production process, although the EMEA has recently authorized its commercialization. ^e See text

Table 3. General Recommendations for Occupational Postexposure Prophylaxis Against HIV

Type of Exposure	Type of Material	Recommended Prophylaxis
Percutaneous	Blood ^a	
	• Very high risk	Recommend
	• High risk	Recommend
	• Risk not high	Offer
	Liquid containing blood, other infectious liquids ^b or tissue.	Offer
	Other body fluids	Do not recommend
Mucous membranes	Blood	Offer
	Liquid containing blood, other infectious liquids ^b or tissue.	Offer
	Other body fluids	Do not recommend
High-risk cutaneous ^c	Blood	Offer
	Liquid containing blood, other infectious liquids ^b or tissue.	Offer
	Other body fluids	Do not recommend

^a **Very high risk** is defined as an accident involving a large volume of blood (deep needlestick with a needle used for venous access) and a high HIV viral load (seroconversion or advanced-phase disease).

High risk is defined as an accident involving a large volume of blood or an accident with blood containing a high HIV viral load

Not high is defined as an accident in which there is no exposure to a large volume of blood or to blood with a high HIV viral load (needlestick with a suture needle in the case of a patient in an asymptomatic phase of HIV infection with a low or undetectable viral load)

^b These include semen, vaginal secretions, cerebrospinal fluid, and synovial, pleural, peritoneal, pericardial, and amniotic fluid.

^c High-risk skin contacts in the case of liquids with a high HIV viral load, prolonged contact, wide surface area, or areas of unbroken skin.

Table 4. Risk of Transmission of HIV After Exposure to an Infected Source

Type of Exposure	Estimated Risk of Transmission of HIV (%)
Blood transfusion (1 unit)	90 - 100
Receptive anal intercourse	0.1 - 3.0
Receptive vaginal intercourse	0.1 – 0.2
Insertive vaginal intercourse	0.03 – 0.09
Insertive anal intercourse	0.06
Receptive oral-genital intercourse	0 – 0.04
Percutaneous needlestick	0.3 (95% CI, 0.2 – 0.5)
Sharing injection material	0.67
Mucosal exposure	0.09 (95% CI, 0.006 – 0.5)

Adapted from Fisher. Int J STD&AIDS 2006 (UK Guideline)

Table 5. Evaluation of the Risk of Sexually Transmitted Infection

HIV-Infected Source Patient		
Appreciable Risk (0.8-3%)	Low Risk (0.05-0.8%)	Minimum Risk (0.01-0.05%)
Anal intercourse with ejaculation ^a	Vaginal intercourse with ejaculation ^a Anal intercourse with ejaculation ^a Vaginal intercourse without ejaculation ^a Anal intercourse ^a Vaginal intercourse ^a Oral-genital sex with ejaculation ^a	Oral sex without ejaculation ^a Woman-to-woman oral-genital sex
Source Patient With HIV Infection Unknown		
Low Risk (0.05-0.08%)	Minimum Risk (0.01-0.05%)	No or Scarce Risk (< 0.01%)
Anal intercourse with ejaculation ^a	Anal intercourse without ejaculation ^a Vaginal intercourse without ejaculation ^a Anal intercourse ^a Vaginal intercourse ^a Oral-genital sex with ejaculation ^a Woman-to-woman oral-genital sex	Kissing Fondling Masturbation Contact between secretions and unbroken skin

^a No condom, breakage of condom, or incorrectly used condom

Table 6. Evaluation of the Risk of HIV Infection by Parenteral Transmission

Appreciable Risk (0.8-3%)	Low Risk (0.05-0.8%)	Minimum Risk (0.01-0.05%)
-Sharing used needles or syringes -Deep needlestick or needlestick with heavy bleeding immediately after use by an unknown source case	-Unknown origin of syringe -Superficial needlestick after use by source case -Heavy contact between source case blood and mucous membranes of affected person.	- Sharing other injecting material - Accidental needlestick with light bleeding from the needle of a syringe whose origin is unknown

Table 7. Risk of HIV Infection According to the Infection Status of the Source Patient

HIV Infection Status in the Source Patient	Risk of HIV Transmission
No HIV infection	No risk
Unknown HIV status or unknown source	Not measured
HIV status unknown, but known source with no risk factors for HIV infection	Low risk
Unknown HIV status, but known source with risk factors for HIV infection	Intermediate risk
Known HIV infection	High risk

Table 8. Types of Exposure

Cutaneous	
Fluids on unbroken skin	Risk no identified
Bite without breaking skin	Risk not identified
Fluids on broken skin (eczema, dermatitis, abrasion, laceration, open wound)	Low-intermediate risk
Skin wound with bleeding in source and recipient	High risk
Percutaneous	
Superficial scratch with a sharp object including needles found in the street	Risk not identified
Puncture wound with a solid needle	Low risk
Puncture wound with a hollow needle and no visible blood	
Body piercing	
Bite with broken skin	
Puncture wound with hollow needle and visible blood	Intermediate risk
Puncture wound with long hollow needle and visible blood or with a recently used needle	High risk
Mucosal	
Kissing	Risk not identified
Oral sex	Low risk
One feed of infected breast milk	
Fluids in the eyes or mouth	
Vaginal intercourse, no trauma	Intermediate risk
Anal intercourse	High risk
Vaginal or anal intercourse with trauma (sexual abuse)	

**FIGURE 1.
STATEMENTS AND SIGNATURES**

WORKER’S STATEMENT:

Dr _____ has satisfactorily explained to me what is involved in occupational postexposure prophylaxis against HIV. He/she has also explained to me the possible benefits, risks, and complications of this prophylaxis, and that there are no other therapeutic possibilities for the same ends. I am aware that there are no absolute guarantees that the result of the treatment will be the most satisfactory. I understand perfectly all the above and **I GIVE MY CONSENT** for the appropriate health care professional to administer the abovementioned prophylaxis.

I can withdraw this consent at any time.

Mr/Miss/Mrs/Ms

National Identity Card Number

Signature of the worker

Date

STATEMENT BY THE LEGAL GUARDIAN OR RELATIVE

I know that the worker Mr/Miss/Mrs/Ms

- Delegates his/her responsibility to me
- Is not competent to take decisions at this time
- Freely wishes, in the presence of witnesses, to share with me his/her decision, with no detriment to the confidentiality required in this case

Dr _____ has satisfactorily explained to me what is involved in occupational postexposure prophylaxis against HIV. He/she has also explained to me the possible benefits, risks, and complications of this prophylaxis, and that there are no other therapeutic possibilities for the same ends. I am aware that there are no absolute guarantees that the result of the treatment will be the most satisfactory. I understand perfectly all the above and **I GIVE MY CONSENT** for the appropriate health care professional to administer the abovementioned prophylaxis.

I can withdraw this consent at any time.

Legal tutor or relative Mr/Miss/Mrs/Ms

National Identity Card Number

Signature of the legal guardian or relative

Date

STATEMENT BY THE PHYSICIAN

I, Dr _____, have informed this worker and/or his/her legal guardian or relative of the purpose and nature of the prophylaxis to be administered after occupational exposure to HIV, as well as the possible benefits, risks, alternative options, and expected results.

Physician’s signature

Date

IF YOU ACCEPT THAT YOU HAVE RECEIVED ADEQUATE INFORMATION AND AGREE TO UNDERGO PROPHYLAXIS AFTER OCCUPATIONAL EXPOSURE TO HIV, BUT DO NOT AGREE TO SIGN THIS DOCUMENT, PLEASE GIVE THE REASONS FOR YOUR DECISION.

.....
.....

Name of the witness

National Identity Card Number

Signature of the witness

Date

IF YOU ACCEPT THAT YOU HAVE RECEIVED ADEQUATE INFORMATION BUT DO NOT AGREE TO UNDERGO PROPHYLAXIS AFTER OCCUPATIONAL EXPOSURE TO HIV, PLEASE SIGN THE REFUSAL AND GIVE THE REASONS FOR YOUR DECISION.

.....
.....

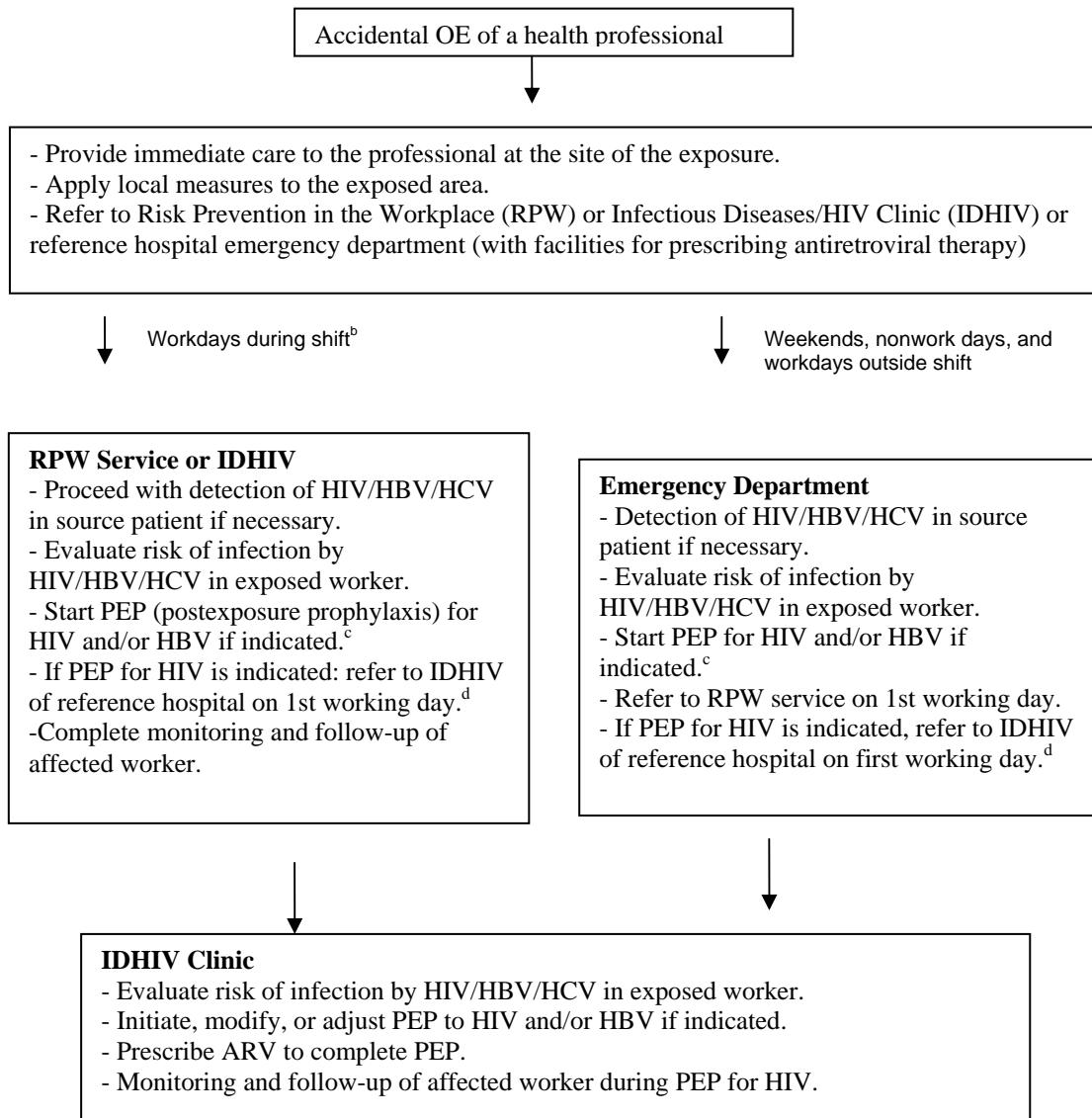
Worker, legal guardian or relative

National Identity Card Number

Signature

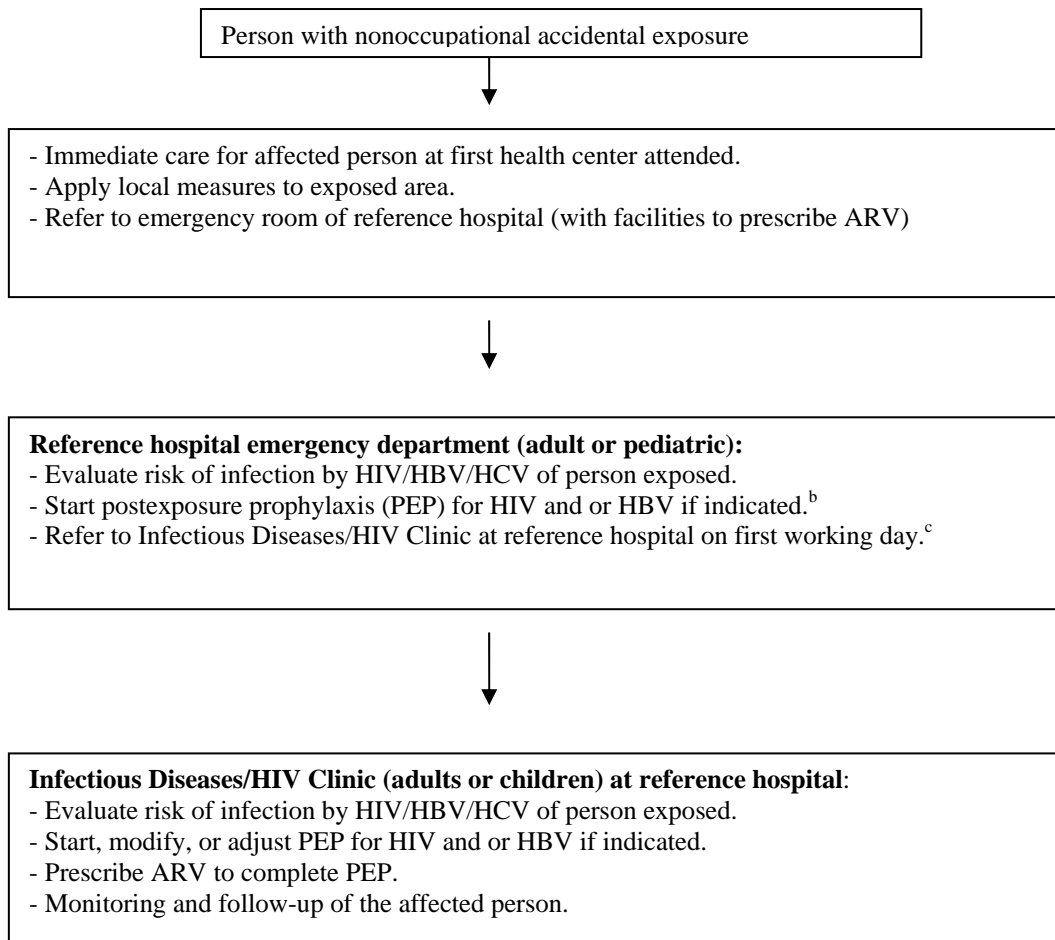
Date

FIGURE 2.
ALGORITHM FOR ACCIDENTAL OCCUPATIONAL EXPOSURE (OE) TO BIOLOGICAL MATERIAL^a



^a This algorithm will be adapted to the characteristics of each hospital
^b Refer to RPW Service or IDHIV according to characteristics of each hospital
^c 24-hour access to the hospital pharmacy is necessary in order to obtain ARV and/or have available a small stock of drugs in the emergency department. The exposed person should receive the necessary dose of ARV until he/she can attend the IDHIV.
^d If patient is attended in the RPW Service or emergency department during a shift, refer to IDHIV on same day.

FIGURE 3.
ALGORITHM FOR NONOCCUPATIONAL EXPOSURE TO BIOLOGICAL MATERIAL^a



^aThis algorithm can be adapted to the particular characteristics of each hospital

^b24-hour access to the hospital pharmacy is mandatory in order to obtain ARV and/or have a small stock of drugs in the emergency department. The exposed person should be given a sufficient amount of medication until it is possible to attend the Infectious Diseases/HIV Clinic.

^cIf attendance at the emergency department is during working hours, the patient should be referred to the Infectious Diseases/HIV Clinic on the same day.

**FIGURE 4
STATEMENTS AND SIGNATURES**

STATEMENT OF PERSON EXPOSED

Dr _____ has satisfactorily explained to me what is involved in nonoccupational postexposure prophylaxis against HIV. He/she has also explained to me the possible benefits, risks, and complications of this prophylaxis, and that there are no other therapeutic possibilities for the same ends. I am aware that there are no absolute guarantees that the result of the treatment will be the most satisfactory. I understand perfectly all the above and **I GIVE MY CONSENT** for the appropriate health care professional to administer the abovementioned prophylaxis.

I can withdraw this consent at any time.

Mr/Miss/Mrs/Ms _____ National Identity Card Number _____
Signature of the person exposed _____ Date _____

STATEMENT BY THE LEGAL GUARDIAN OR RELATIVE

I know that the worker Mr/Miss/Mrs/Ms

- Delegates his/her responsibility to me
- Is not competent to take decisions at this time
- Freely wishes, in the presence of witnesses, to share with me his/her decision, with no detriment to the confidentiality required in this case

Dr _____ has satisfactorily explained to me what is involved in occupational postexposure prophylaxis against HIV. He/she has also explained to me the possible benefits, risks, and complications of this prophylaxis, and that there are no other therapeutic possibilities for the same ends. I am aware that there are no absolute guarantees that the result of the treatment will be the most satisfactory. I understand perfectly all the above and **I GIVE MY CONSENT** for the appropriate health care professional to administer the abovementioned prophylaxis.

I can withdraw this consent at any time.

Legal tutor or relative Mr/Miss/Mrs/Ms _____ National Identity Card Number _____
Signature of the legal guardian or relative: _____ Date _____

STATEMENT BY THE PHYSICIAN

I, Dr _____, have informed this worker and/or his/her legal guardian or relative of the purpose and nature of the prophylaxis to be administered after occupational exposure to HIV, as well as the possible benefits, risks, alternative options, and expected results.

Physician's signature _____ Date _____

IF YOU ACCEPT THAT YOU HAVE RECEIVED ADEQUATE INFORMATION AND AGREE TO UNDERGO PROPHYLAXIS AFTER OCCUPATIONAL EXPOSURE TO HIV, BUT DO NOT AGREE TO SIGN THIS DOCUMENT, PLEASE GIVE THE REASONS FOR YOUR DECISION.

.....
.....

Name of the witness _____ National Identity Card Number _____
Signature of the witness _____ Date _____

IF YOU ACCEPT THAT YOU HAVE RECEIVED ADEQUATE INFORMATION BUT DO NOT AGREE TO UNDERGO PROPHYLAXIS AFTER OCCUPATIONAL EXPOSURE TO HIV, PLEASE SIGN THE REFUSAL AND GIVE THE REASONS FOR YOUR DECISION.

.....
.....

Worker, legal guardian or relative _____ National Identity Card Number _____
Signature _____ Date _____

Expert Panel of the National AIDS Plan Secretariat (SPNS), AIDS Study Group (GESIDA), Center for Epidemiologic Studies of STI and AIDS in Catalonia (CEEISCAT), Spanish Society of Pediatric Infections (SEIP), and the Spanish Pediatric Association (AEP)

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