UPDATED POST EXPOSURE PROPHYLAXIS (PEP) KIT CONTENTS

S9901023 -IEHK2017, PEP kit

unicef
for every child

Supply Division, Copenhagen

Background

The "Interagency Emergency Health Kit 2017 (IEHK2017)" has been updated to take into account the intersessional changes to the IEHK2017 PEP kit. The changes were based on the updated WHO recommendations on the first line and second line antiretroviral regimens and post exposure prophylaxis (PEP). https://cdn.who.int/media/docs/defaultsource/documents/emergencies/supplies/iehk2017-info-5january2021.pdf?sfvrsn=be9149f5_8.

The IEHK PEP kit contains medicines for emergency post-exposure prophylaxis of HIV infection and presumptive treatment of other Sexually Transmitted Infections (STIs) following sexual assault. It also contains emergency contraceptives and pregnancy test kits

What has changed?

1. The Anti-Retroviral (ARV) Medicines recommended for HIV PEP for adults and children have changed
2. The recommended ARV medicines for adults and children now includes Dolutegravir.
3. The ARV regimen for HIV PEP contains three medicines for both adults and children

Important Action Points

- The price for the updated IEHK PEP is USD 1366, up from USD 1362. Remember to allocate adequate budget for the target number of kits.
- Some of the ARV medicines in this kit may have valid intellectual property rights (including patents) filed by the patent owners in your country. If that is the case, we recommend that the country considers to make use of TRIPS flexibilities such as "for government use "clause, citing this as emergency supplies. This will enable importation of the kit into your country without infringing on patent rights. You can view patent status at: medicines patent and license database
- Inform partners/programme colleagues of these changes
- Organize a Country based forum to review the information in this technical bulletin and plan to update any relevant country documents. This may include Country Emergency Supply Lists and guidance to health care providers on use of the Revised IEHK PEP kit. (See useful information in Annex 1)

OVERVIEW OF CONTENTS OF OLD AND REVISED IEHK PEP KIT

Previous IEHK2017 PEP kit content				Revised Intersessional IEHK PEP kit content			
UNICEF material number	**UNICEF material description**	**Qty**	**Remarks**	**UNICEF material number**	**UNICEF material description**	**Qty**	**Remarks**
S1531011	Azithromycin pdr/or s 200mg/5ml/BOT-15ml	10	No change	S1531011	Azithromycin pdr/or s 200mg/5ml/BOT-15ml	10	No change
S1504003	Cefixime pwd.for sus.100mg/5ml/BOT50ml	10	No change	S1504003	Cefixime pwd.for sus.100mg/5ml/ BOT50ml	10	No change
S1400649	3TC30mg+AZT60mg disp. tabs/PAC-60 gb	**30**	**Removed**	**S1400643**	**ABC120mg+3TC60mg disp. tabs/ PAC-60 gb**	**15**	**New**
S1400541	LPV/r 200+50mg heat/st tabs/PAC-120 gb	**4**	**Removed**	**S1400653**	**Dolutegravir 50mg tabs/PAC-30 gb**	**9**	**New**
S1400576	LPV/r 100+25mg heat/st tabs/PAC-60 gb	**3**	**Removed**	**S1400651**	**Dolutegravir 10mg disp tab/PAC-90 No CTN**	**1**	**New**
S0584502	HCG Pregnancy rapid Test, kit/50	2	Change of pack size	S0584504	WondfoOn-eStepHCGUrinTest,Midstream,kit/1	50	Different pack size
S1400630	3TC300mg+TDF300mg tabs/PAC-30 gb	50	**Removed**	**S1400652**	**DTG50mg+3TC300mg+TDF300mg tabs/PAC-30 gb**	**50**	**New**
S1400598	ATV/r 300mg+100mg tabs/ PAC-30 gb	50	**Removed**				
S1514130	Levonorgestrel 750mcg tabs/PAC-2 (I)	50	No change	S1514130	Levonorgestrel 750mcg tabs/PAC-2 (I)	50	No change
S1531009	Azithromycin 250mg tablets/ PAC-6	34	No change	S1531009	Azithromycin 250mg tablets/PAC-6	34	No change
S1531002	Cefixime 200mg tablets/ PAC-56	2	No change	S1531002	Cefixime 200mg tablets/PAC-56	2	No change

S9901023 -IEHK2017, PEP KIT PACKING

In response to country office requests to SD to further facilitate the in-country distribution of the kit, SD has made three sub-kits consisting of:

- 2 adult sub kits, each targeting 25 adults
- 1 paediatric sub kit, targeting 10 children

The entire S9901023 -IEHK2017, PEP KIT must be ordered as such i.e. the sub-kits cannot be ordered on their own.

Contents of the sub kits

Material number	Item description	UOM	Total quantity	Adult sub kit 1	Adult sub kit 2	Paed sub kit
S1531011	Azithromycin pdr/or s 200mg/5ml/BOT-15ml	PAC	10	0	0	20
S1531009	Azithromycin 250mg tablets/PAC-6	PAC	34	17	17	0
S1504003	Cefixime pwd.for sus.100mg/5ml/BOT50ml	PAC	10	0	0	10
S1531002	Cefixime 200mg tablets/PAC-56	PAC	2	1	1	0
S1514130	Levonorgestrel 750mcg tabs/PAC-2 (I)	EA	50	25	25	0
S0584504	WondfoOneStepHCGUrinTest,Midstream,kit/1	EA	50	25	25	0
S1400652	DTG50mg+3TC300mg+TDF300mg tabs/PAC-30 gb	EA	50	25	25	0
S1400643	ABC120mg+3TC60mg disp. tabs/PAC-60 gb		15	0	0	15
S1400653	Dolutegravir 50mg tabs/PAC-30 gb	EA	9	0	0	9
S1400651	Dolutegravir 10mg disp tab/PAC-90 No CTN	EA	2	0	0	2

For any queries or comments, please contact the Supply Division Medicines and Nutrition Centre at: supply@unicef.org.

ANNEX 1: SUPPLEMENTARY INFORMATION TO GUIDE USE OF IEHK2017 PEP KIT CONTENTS

According to the WHO Clinical management of rape and intimate partner violence survivors; https://www.who.int/reproductivehealth/publications/rape-survivors-humanitarian-settings/en/

The essential components of medical care after a sexual assault are:

- Documentation of Injuries
- Collection of forensic evidence
- Treatment of injuries
- Evaluation for Sexually transmitted infections and preventive care
- Psychosocial support, counselling and follow-up

This Annex provides background information to support the use of IEHK PEP kit contents for

- Post Exposure Prophylaxis of HIV
- Presumptive treatment of sexually transmitted infections (STI).
- Prevention of pregnancy

POST EXPOSURE PROPHYLAXIS OF HIV

Testing for HIV is NOT mandatory before offering PEP. Declining an HIV test or non-availability of HIV testing should never be a barrier to initiating PEP.

Post exposure prophylaxis of HIV should be provided as soon as possible after sexual assault, and within 72 hours**.** Post-exposure prophylaxis is not indicated if the exposed person is known or confirmed to be HIV positive.

RAPID DIAGNOSTIC TEST KITS (RDTs) FOR HIV ARE NOT included in the IEHK PEP kit

Where testing for HIV is offered before starting PEP, ensure to obtain consent to test after explaining the risks and benefits of testing**.** A follow up test should be done three months after potential exposure to HIV.

A positive rapid HIV antibody test result four weeks after the sexual assault cannot confirm if someone has been infected during the assault. Such a test result must be confirmed before a diagnosis of infection can be given.
Ideally, RDT tests that can provide definitive results are recommended (ELISA).

PRESUMPTIVE TREATMENT OF SEXUALLY TRANSMITTED INFECTIONS (STI).

Diagnosis
STI diagnosis is not mandatory before offering presumptive treatment; WHO recommends presumptive treatment of Sexually Transmitted Infections (STI) in the context of sexual assault or other emergency contexts, especially in areas with high prevalence of STIs. The decision about whether to provide presumptive treatment or wait for results of STI tests should be based on assessment of exposure risk and consent of the survivor

Presumptive Treatment

The incubation period of different STIs varies from a few days for gonorrhoea and chancroid to weeks or months for syphilis and HIV.

The STIs covered by standard Presumptive treatment are those caused by

- Neisseria gonorrhoeae
- Chlamydia trachomatis
- Treponema pallidum (syphilis)

Health care provider should offer presumptive treatment for STI after explaining the risks and benefits and obtaining informed consent from the survivor.

STI regimens can start on the same day as emergency contraception and post-exposure prophylaxis for HIV (PEP), although the doses should be spread out (and taken with food) to reduce side-effects, such as nausea.

Recommended STI Regimen- Children
Single dose Azithromycin 20 mg/kg orally **AND** Single dose Cefixime* 8 mg/kg orally.

* Single dose Ceftriaxone 250 mg (Not included in the kit) Intramuscular Injection can replace Cefixime If there is high N. gonorrhoea bacterial resistance to Cefixime

Metronidazole (Not included in the kit) 5 mg/kg every 8 hours/day for 7 days can be added to the above regimen ONLY if Trichomonas vaginalis is prevalent

Recommended Regimen-Adolescents and adults
Single dose Azithromycin 1g orally **AND** Single dose Cefixime* 400mg orally

* Single dose Ceftriaxone 250 mg (Not in the IEHK PEP kit) Intramuscular Injection can replace Cefixime If there is high N. gonorrhoea bacterial resistance to Cefixime

Metronidazole (Not in the IEHK PEP kit) 2g orally as a single dose. can be added to the above regimen ONLY if Trichomonas vaginalis is prevalent. Metronidazole is contraindicated in first trimester of pregnancy

NOTE: Metronidazole tablets/oral liquid and Ceftriaxone Injection are not included in the IEHK PEP Kit but can be accessed directly from UNICEF

WHO recommended Anti-Retroviral (ARV) regimens for post-exposure prophylaxis for HIV infections among adults, adolescents and children.

Recommendation	Strength of the recommendation	Quality of the Evidence
Number of antiretroviral drugs		
An HIV post-exposure prophylaxis regimen with two antiretroviral drugs is effective, but three drugs are preferred	Conditional	Low
Preferred antiretroviral regimen for adults and adolescents		
Tenofovir (TDF) + Lamivudine (3TC) [or Emtricitabine- FTC] is recommended as the preferred backbone regimen for HIV post exposure prophylaxis among adults and adolescents.	Strong	Low to moderate
Dolutegravir is recommended as the preferred third drug for HIV post-exposure prophylaxis among adults and adolescents.	Strong	Low
When available, Atazanavir/ritonavir (ATV/r), Darunavir/ritonavir (DRV/r), Lopinavir/ritonavir (LPV/r) and Raltegravir (RAL) may be considered as alternative third drug options for HIV post exposure prophylaxis among adults and adolescents.	Conditional	low
Preferred antiretroviral regimen for children ≤10 years old		
Zidovudine (AZT) + Lamivudine (3TC) is recommended as the preferred backbone regimen for HIV post-exposure prophylaxis among children 10 years and younger Abacavir (ABC) + Lamivudine (3TC) or TDF + 3TC (or FTC) can be considered as alternative regimens.	Strong	Low
Dolutegravir is recommended as the preferred third drug for HIV post-exposure prophylaxis among children	Strong	Low
When available, Atazanavir/ritonavir (ATV/r), Darunavir/ritonavir (DRV/r), Lopinavir/ritonavir (LPV/r) and Raltegravir (RAL) may be considered as alternative third drug options for HIV post exposure prophylaxis	Conditional	low
Prescribing frequency		
A 28-day prescription of antiretroviral drugs should be provided for HIV post-exposure prophylaxis following initial risk assessment.	Strong	Very Low
Adherence support		
Enhanced adherence counselling is suggested for all individuals initiating HIV post-exposure prophylaxis.	Conditional	Moderate

Adapted from World Health Organization (WHO) Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery And Monitoring: Recommendations For A Public Health Approach
https://www.who.int/publications/i/item/9789240031593

Recommended regimen for HIV prevention for IEHK PEP KIT-Adult

Lamivudine (3TC) 300mg + Tenofovir (TDF) 300mg + Dolutegravir (DTG) 50mg tablet. 1 tablet once daily for 28 days

Recommended Regimen for HIV prevention for IEHK PEP KIT- Children

To be administered as per dosing table below for 28 days
backbone regimen selected - Abacavir (ABC) 120mg+ Lamivudine (3TC) 60mg
With third drug – Dolutegravir (DTG) 50mg or 10mg dispersible tablets (according to the weight)

Simplified dosing of child friendly solid formulations for once daily dosing for infants and children four weeks and older.

Drug	Strength of paediatric tablet	Number of tablets or capsules by weight band once daily					Strength of adult tablet	
		3–<6 kg	6–<10 kg	10–<14 kg	14–<20 kg	20–<25 kg		25–<35 kg
DTG	Film-coated tablet 50 mg	—	—	—	—	1	50mg	1
	Dispersible tablet 5 mg	1	3	4	5	6		
	Dispersible scored tablet 10 mg	0.5	1.5	2	2.5	3		
ABC/3TC	Tablet (dispersible) 60 mg/30 mg	2	3	4	5	6	600mg/300mg	1
	Tablet (dispersible) 120 mg/60 mg	1	1.5	2	2.5	3		

Adapted from World Health Organization (WHO) Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery And Monitoring: Recommendations For A Public Health Approach
https://www.who.int/publications/i/item/9789240031593

PRESUMPTIVE TREATMENT OF SEXUALLY TRANSMITTED INFECTIONS (STI).

Diagnosis

STI diagnosis is not mandatory before offering presumptive treatment; WHO recommends presumptive treatment of Sexually Transmitted Infections (STI) in the context of sexual assault or other emergency contexts, especially in areas with high prevalence of STIs. The decision about whether to provide presumptive treatment or wait for results of STI tests should be based on assessment of exposure risk and consent of the survivor

Presumptive Treatment

The incubation period of different STIs varies from a few days for gonorrhoea and chancroid to weeks or months for syphilis and HIV.

The STIs covered by standard Presumptive treatment are those caused by

- Neisseria gonorrhoeae
- Chlamydia trachomatis
- Treponema pallidum (syphilis)

Health care provider should offer presumptive treatment for STI after explaining the risks and benefits and obtaining informed consent from the survivor.

STI regimens can start on the same day as emergency contraception and post-exposure prophylaxis for HIV (PEP), although the doses should be spread out (and taken with food) to reduce side-effects, such as nausea.

Recommended STI Regimen- Children

Single dose Azithromycin 20 mg/kg orally **AND** Single dose Cefixime* 8 mg/kg orally.

* Single dose Ceftriaxone 250 mg (Not included in the kit) Intramuscular Injection can replace Cefixime If there is high N. gonorrhoea bacterial resistance to Cefixime

Metronidazole (Not included in the kit) 5mg/kg every 8 hours/day for 7 days can be added to the above regimen ONLY if Trichomonas vaginalis is prevalent

Recommended Regimen-Adolescents and adults

Single dose Azithromycin 1g orally **AND** Single dose Cefixime* 400mg orally

* Single dose Ceftriaxone 250mg (Not in the IEHK PEP kit) Intramuscular Injection can replace Cefixime If there is high N. gonorrhoea bacterial resistance to Cefixime.

Metronidazole (Not in the IEHK PEP kit) 2g orally as a single dose. can be added to the above regimen ONLY if Trichomonas vaginalis is prevalent. Metronidazole is contraindicated in first trimester of pregnancy

NOTE: Metronidazole tablets/oral liquid and Ceftriaxone Injection are not included in the IEHK PEP Kit but can be accessed directly from UNICEF

PREVENTION OF PREGNANCY

Pregnancy testing

Pregnancy risk assessment and Medical eligibility criteria for using the different options for emergency contraception should be based on country national guidelines and preferably conducted by a duly qualified health professional. Before giving emergency contraceptive pills, Pregnancy test should be offered to the sexual assault survivor to rule out pre-existing pregnancy.

Emergency contraception

Emergency contraception should be offered to female survivors of sexual assault at risk of becoming pregnant. Health care provider should explain the risks and benefits of the available emergency contraception methods and obtain informed consent from the survivor before initiating emergency contraception.

Emergency contraception is only effective if used as soon as possible after unprotected sexual intercourse and before ovulation; generally, they do not add value if used more than 5 days after unprotected intercourse. Levonorgestrel, the emergency contraceptive in the IEHK PEP kit has label claim to be effective up to 72 hours (3 days) after unprotected sexual intercourse. Although it has demonstrated effectiveness up to 96 hrs, effectiveness beyond 72 hours is outside the product license

Levonorgestrel should be taken as a single dose (1.5 mg) or alternatively, in 2 doses (0.75 mg each, 12 hours apart). Evidence indicates that it prevents pregnancy in 52–94% of situations.

Ulipristal acetate (Not included in IEHK PEP Kit), taken as a single dose at 30 mg is an alternative to Levonorgestrel. Evidence indicates that it prevents pregnancy in at least 98% of situations, especially if taken within 72 hours of sexual intercourse

In addition to Emergency Contraceptive Pills (ECPs), WHO recommends 2 other methods of emergency contraception, not included in the IEHK PEP Kit: (Adapted from WHO FACT SHEET on emergency contraception https://www.who.int/news-room/fact-sheets/detail/emergency-contraception, accessed 7th December 2021)

1. Combined Oral Contraceptive Pills or the Yuzpe method.

Combined Oral contraceptive pills are to be taken in 2 doses. Each dose must contain estrogen (100 –120 mcg ethinyl estradiol) and progestin (0.50–0.60 mg levonorgestrel (LNG) or 1.0–1.2 mg norgestrel). The first dose should be taken as soon as possible after unprotected intercourse (preferably within 72 hours but as late as 120 hours, or 5 days) and the second dose should be taken 12 hours later. If vomiting occurs within 2 hours of taking a dose, the dose should be repeated.

2. Copper-bearing intrauterine devices (IUDs)

This is the most effective form of emergency contraception available. The IUD should be inserted within 5 days of unprotected intercourse. When inserted within 5 days of unprotected intercourse, a copper-bearing IUD is over 99% effective in preventing pregnancy. Once inserted, the IUD can be left in place for as long as 12 years or more as an ongoing reversible method of contraception.

The additional emergency contraceptive methods can normally be obtained from UNFPA