Highlights of the 2017 European AIDS Clinical Society (EACS) Guidelines for the treatment of adult HIV-positive persons version 9.0
the EACS Governing Board

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Highlights of the 2017 European AIDS Clinical Society (EACS) Guidelines for the treatment of adult HIV-positive persons version 9.0

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Background
The European AIDS Clinical Society (EACS) Guidelines have since 2005 provided multidisciplinary recommendations for the care of HIV-positive persons in geographically diverse areas.

Guideline highlights
Major revisions have been made in all sections of the 2017 Guidelines: antiretroviral treatment (ART), comorbidities, coinfections and opportunistic diseases. Newly added are also a summary of the main changes made, and direct video links to the EACS online course on HIV Management. Recommendations on the clinical situations in which tenofovir alafenamide may be considered over tenofovir disoproxil fumarate are provided, and recommendations on which antiretrovirals can be used safely during pregnancy have been revised. Renal and bone toxicity and hepatitis C virus (HCV) treatment have been added as potential reasons for ART switches in fully virologically suppressed individuals, and dolutegravir/rilpivirine has been included as a treatment option. In contrast, dolutegravir monotherapy is not recommended. New recommendations on non-alcoholic fatty liver disease, chronic lung disease, solid organ transplantation, and prescribing in elderly are included, and human papilloma virus (HPV) vaccination recommendations have been expanded. All drug–drug interaction tables have been updated and new tables are included. Treatment options for direct-acting antivirals (DAAs) have been updated and include the latest combinations of sofosbuvir/velpatasvir/voxilaprevir and glecaprevir/pibrentasvir. Recommendations on management of DAA failure and acute HCV infection have been expanded. For treatment of tuberculosis (TB), it is underlined that intermittent treatment is contraindicated, and for resistant TB new data suggest that using a three-drug combination may be as effective as a five-drug regimen, and may reduce treatment duration from 18-24 to 6-10 months.

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Conclusions
Version 9.0 of the EACS Guidelines provides a holistic approach to HIV care and is translated into the six most commonly spoken languages.

Keywords: antiretroviral treatment, ART, coinfections, comorbidities, European AIDS Clinical Society guidelines, HBV, HCV, HIV, opportunistic diseases

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The European AIDS Clinical Society (EACS) Guidelines

The European AIDS Clinical Society (EACS) Guidelines were revised in 2017 for the 12th time (including interim updates) since the Guidelines were first developed in 2005 [1]. The Guidelines aim to cover a relatively large and diverse area geographically, with very different national levels of access to care. As a natural consequence, the EACS Guidelines provide a wider range of recommendations than the often much more uniform national guidelines. The aims of the EACS Guidelines to provide easily accessible and comprehensive multidisciplinary recommendations to clinicians involved in the care of HIV-positive individuals have previously been described in detail [2].

Major revisions have been made in all main sections: visit assessment, antiretroviral treatment (ART), comorbidities, coinfections and opportunistic diseases. Newly introduced in version (v.) 9.0 is a section summarizing the main changes made since the release of the last interim update (v.8.2) of the Guidelines. In previous years, this summary page was only available online on the EACS website, but it is now included in the Guidelines themselves.

Also new in the 2017 version are direct video links to the EACS online course on HIV Management. These links can be found throughout the Guidelines in the respective sections and collated on the last page of the Guidelines. There is no need to register or to sign in as the online courses are freely available for all by simply clicking the video link.

The EACS Guidelines v.9.0 have been translated into the six most commonly spoken languages, Spanish, Portuguese, French, Russian, German and Chinese, and are available online (www.eacsociety.org/guidelines/eacs-guidelines/eacs-guidelines.html), in print as a booklet and as a free app for iOS and Android devices produced with the Sanford Group.

The Guidelines group warmly welcome comments on the Guidelines, which can be submitted via guidelines@eacsociety.org.

The review process

The EACS Guidelines undergo systematic minor revisions annually and major systematic revisions biennially. Additional interim updates make it possible to incorporate any new important data in a timely fashion, and ensure that the Guidelines remain up to date.

Each section of the Guidelines is managed by a panel of European HIV experts and additional experts where relevant (e.g. a cardiologist, oncologist and pulmonologist in the Comorbidity section) (see Appendix 1). Details of the Guidelines management have been reported previously [2].

The Guidelines are extensively cross-reviewed by the panel members with input from representatives from Women against Viruses in Europe (WAVE) and the community. EACS further collaborates with linguists, designers, app developers and translators to produce the three final versions of the Guidelines.

In the following sections, the most important changes made in 2017 for each section of the Guidelines are described in more detail.

ART section

Only drugs currently licensed by the European Medicines Agency (EMA) are taken into consideration in the Guidelines. The EACS Guidelines continue to recommend six preferred ART regimens for ART-naïve adults: four integrase inhibitor (INSTI)-based, one nonnucleoside reverse transcriptase inhibitor (NNRTI)-based, and one ritonavir/ cobicistat (COBI)-boosted protease inhibitor (PI/r or PI/c)-based (Table 1). As alternative regimens, to be used when none of the preferred regimens are feasible or available, seven options are currently recommended: one INSTI-based, two NNRTI-based, three boosted PI-based and one combining raltegravir (RAL) and boosted darunavir (DRV/r or DRV/c). The alternative regimens are ordered by preference of use, whereas the preferred regimens are considered equally effective. The older PI/r lopinavir/r was this year removed from the list of alternative suggested PIs.

Added in 2017 is an expert recommendation on the clinical situations in which use of tenofovir alafenamide (TAF) may be considered over tenofovir disoproxil fumarate (TDF), while still acknowledging that long-term follow-up data on TAF is pending.
Table 1 Initial combination regimens for antiretroviral therapy (ART)-naïve adult HIV-positive persons. (A) Recommended regimens (one of the following to be selected)*,†. (B) Alternative regimens (to be used when none of the preferred regimens are feasible or available, whatever the reason)

### A

| Regimen | Dosing | Caution | Food requirement |
|---------|--------|---------|-----------------|
| 2 NRTIs + INSTI | ABC/3TC/DTG | ABC/3TC/DTG 600/300/50 mg, 1 tablet qd | Co-administration of antacids containing Al or Mg not recommended. RAL 400 or 800 mg bid with rifampicin | None |
| TDF/FTC | TDF/FTC 300 mg, 1 tablet qd | |
| +DTG | +DTG 50 mg, 1 tablet qd | |
| TAF/FTC/EVG | TAF/FTC/EVG 10/200/150 mg, 1 tablet qd | |
| or TDF/FTC/EVG | TDF/FTC/EVG 300/200/150 mg, 1 tablet qd | |
| TAF/FTC or TDF/FTC | TAF/FTC 25/200 mg, 1 tablet qd | |
| +RAL | +RAL 400 mg, 1 tablet bid | |
| 2 NRTIs + NNRTI | ABC/3TC/EFV | ABC/3TC 600/300 mg, 1 tablet qd + EFV 600 mg, 1 tablet qd | Only if HIV-VL < 100 000 copies/mL At bed time or 2 h before dinner | With food |
| TDF/FTC/EFV | TDF/FTC/EFV 300/200/600 mg, 1 tablet qd | |
| 2 NRTIs + PI/r or PI/c | TAF/FTC or TDF/FTC | TAF/FTC 10/200 mg, 1 tablet qd | Monitor in persons with a known sulfonamide allergy | With food |
| +ATV/c** | +ATV/c 300/150 mg, 1 tablet qd | |
| or +ATV/r†† | +ATV/c 300/150 mg, 1 tablet qd | |
| ABC/3TC | ABC/3TC 600/300 mg, 1 tablet qd | |
| +ATV/c** | +ATV/c 300/150 mg, 1 tablet qd | |
| or +ATV/r†† | +ATV 300 mg, 1 tablet qd + RTV 100 mg, 1 tablet qd | |
| ABC/3TC | ABC/3TC 600/300 mg, 1 tablet qd | |
| +DRV/c** | +DRV/c 800/150 mg, 1 tablet qd | |
| or +DRV/r†† | +DRV 800 mg, 1 tablet qd + RTV 100 mg, 1 tablet qd | |

### B

| Regimen | Dosing | Caution | Food requirement |
|---------|--------|---------|-----------------|
| 2 NRTIs + INSTI | ABC/3TC/RAL | ABC/3TC 600/300 mg, 1 tablet qd + RAL 400 mg, 1 tablet qd | Co-administration of antacids containing Al or Mg not recommended. RAL 400 or 800 mg bid with rifampicin | None |
| TDF/FTC | TDF/FTC 300 mg, 1 tablet qd | |
| 2 NRTIs + NNRTI | ABC/3TC/EFV | ABC/3TC 600/300 mg, 1 tablet qd + EFV 600 mg, 1 tablet qd | Only if HIV-VL < 100 000 copies/mL At bed time or 2 h before dinner | With food |
| TDF/FTC/EFV | TDF/FTC/EFV 300/200/600 mg, 1 tablet qd | |
| 2 NRTIs + PI/r or PI/c | TAF/FTC or TDF/FTC | TAF/FTC 10/200 mg, 1 tablet qd | Monitor in persons with a known sulfonamide allergy | With food |
| +ATV/c** | +ATV/c 300/150 mg, 1 tablet qd | |
| or +ATV/r†† | +ATV/c 300/150 mg, 1 tablet qd | |
| ABC/3TC | ABC/3TC 600/300 mg, 1 tablet qd | |
| +ATV/c** | +ATV/c 300/150 mg, 1 tablet qd | |
| or +ATV/r†† | +ATV 300 mg, 1 tablet qd + RTV 100 mg, 1 tablet qd | |
| ABC/3TC | ABC/3TC 600/300 mg, 1 tablet qd | |
| +DRV/c** | +DRV/c 800/150 mg, 1 tablet qd | |
| or +DRV/r†† | +DRV 800 mg, 1 tablet qd + RTV 100 mg, 1 tablet qd | |

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The antiretrovirals considered safe to use during pregnancy have been revised, and now also include efavirenz, RAL, dolutegravir (DTG), rilpivirine (RPV) and DRV/r. As there is still limited experience with TAF and COBI in pregnancy, these are not recommended as part of initial regimens. In the case of a women becoming pregnant while on COBI-boosted elvitegravir (EVG/c), closer monitoring of HIV viral load and drug levels may be necessary, as data from pharmacokinetic studies have found substantially lower levels of EVG/c during pregnancy, which may not be adequate for sustained viral suppression [3,4]. ART containing an INSTI is recommended in women starting treatment in the late second or third trimester to ensure a rapid reduction in viral load. The Guidelines advise against breast feeding. However, if breast feeding is still carried out, it is recommended to increase clinical and virological monitoring of both the mother and the infant.

Renal and bone toxicity and ongoing hepatitis C virus (HCV) treatment have been added as additional reasons for performing drug switches in virologically suppressed populations. For class-sparing options, DTG and RPV have been added as additional options, as has lamivudine (3TC) used in combination with either boosted DRV or atazanavir (ATV). DTG monotherapy is not recommended.

Safety data from the D:A:D study suggesting a cumulative association between use of boosted DRV and incident cardiovascular disease have also been included [5].

Comorbidity section

Entirely new sections on non-alcoholic fatty liver disease (NAFLD), chronic lung disease, solid organ transplantation, and prescribing in elderly have been added in v.9.0, acknowledging the increased prevalence of each of these conditions, and the need for HIV-specific guidance to deal with multimorbidity and potential drug–drug interactions.

In the renal section, an additional dynamic measure of renal impairment (rapid progression of renal function) has been included to allow for earlier detection of worsening renal function. Different scenarios of prevalent or high risk of renal impairment in which TAF may be used over TDF are specified, as has also been done in the bone section.

Acknowledging new recommendations in the general population, blood pressure targets have been lowered to systolic pressure < 130 and diastolic pressure < 80 mmHg for individuals at high risk, for example diabetics, where resources allow. There are, however, still limited data on cardiovascular disease prevention related to the use of oral antidiabetics in HIV-positive persons, and the current management recommendations have been updated to include various combinations of metformin together with other antidiabetics. In HIV-positive persons inadequately controlled on maximum statin doses or intolerant to statins, PCSK9 inhibitors, a new lipid-lowering drug class, may be used.

Table 1 (Continued)

| Regimen | Dosing | Caution | Food requirement |
|---------|--------|---------|------------------|
| Other combinations | RAL³ | RAL 400 mg, 1 tablet bid | Only if CD4 count > 200 cells/µL and HIV-VL. | With food |
| +DRV/c* or +DRV/r** | +DRV/c 800/150 mg, 1 tablet qd or +DRV 805 mg, 1 tablet qd + RTV 100 mg, 1 tablet qd | | |

*Only drugs currently licensed for initiation of therapy by the EMA are taken into consideration (in alphabetical order).

††Generic HIV drugs are becoming more available and can be used as long as they replace the same drug and do not break recommended fixed dose combinations.

ABC contraindicated if HLA-B*5701 positive. Even if HLA-B*5701 negative, counselling on HSR risk still mandatory. ABC should be used with caution in persons with a high CVD risk (> 20%).

Use this combination only if HBsAg-negative.

In certain countries TDF is labeled as 245 mg rather than 300 mg to reflect the concentration of the active metabolite (tenofovir disoproxil). When available, combinations containing TDF can be replaced by the same combinations containing TAF. TAF is used at 10 mg when co-administered with drugs that inhibit P-gp, and at 25 mg when co-administered with drugs that do not inhibit P-gp. The decision whether to use TDF or TAF depends on individual characteristics as well as availability. So far, there are only limited long-term data on TAF. TAF should be considered as a first choice over TDF in individuals with; established or high risk of CKD; co-medication with nephrotoxic drugs or prior TDF toxicity; osteoporosis/progressive osteopenia or risk factors; history of fragility fracture. There are limited data on use of TAF with eGFR < 30 mL/min; Expert opinion pending clinical data.

**TDF/FTC/EVG/c use only if eGFR ≥ 70 mL/min. It is recommended that TDF/FTC/EVG/c is not initiated in persons with eGFR < 90 mL/min unless this is the preferred treatment.

††A single study has shown increase in CVD risk with cumulative use of DRV [13].

EFV: not to be given if history of suicide attempts or mental illness; not active against HIV-2 and HIV-1 group O strains.

Co-administration of PPI is contraindicated. If PPI co-administration is judged unavoidable, consider an alternative regimen; if given, dose increase of ATV to 400 mg qd may be considered, close clinical monitoring is recommended and doses of PPI comparable to omeprazole 20 mg should not be exceeded and must be taken approximately 12 h prior to the ATV/r. H2 antagonists to be taken 12 h before or 4 h after ATV.

*Only drugs currently licensed for initiation of therapy by the EMA are taken into consideration (in alphabetical order).
In the vaccination section, human papilloma virus (HPV) vaccination recommendations have been expanded to include vaccination of all HIV-positive persons up to the age of 26 years, or 40 years in the case of men who have sex with men, with three doses of the 9-valent vaccine. The vaccination effect is, however, questionable in the case of already prevalent HPV infection.

The current screening recommendation for anal cancer has been extended to also include persons with evidence of HPV-related dysplasia. Also, for cervical cancer, the screening recommendation has been expanded to include all HIV-positive women within 1 year after sexual debut or > 21 years of age.

Screening for hepatocellular carcinoma (HCC) is indicated in all persons with cirrhosis, regardless of the underlying reason. Screening should also be performed systematically in persons without cirrhosis with hepatitis B virus (HBV) coinfection at high HCC risk (i.e. a family history) or with chronic hepatitis.

Drug–drug interaction tables
The drug–drug interaction tables in the EACS Guidelines provide an overview of the potential for interactions between individual antiretroviral drugs and the most commonly used comediations within a therapeutic area.

All drug–drug interaction tables in v.9.0 have been updated with the addition of COBI-boosted atazanavir (ATV/c) which has been licensed since the last Guidelines update.

Entirely new drug–drug interaction tables have additionally been included on drugs used for treating chronic lung disease and pulmonary hypertension and immunosuppressants used in solid organ transplantation.

Changes to the existing tables include a strong recommendation against the coadministration of potent steroids with boosted regimens because of the increased risk of developing Cushing syndrome.

Also, the contraceptive table has been updated to include various contraceptive methods to better discriminate between drug–drug interactions associated with a risk of contraceptive failure and those unlikely to impair efficacy.

Detailed information on drug–drug interactions can be found at the University of Liverpool website: www.hiv-druginteractions.org.

Coinfection section
In the coinfection section, details on older regimens used for treating HCV coinfection including ribavirin (RBV) and interferon (IFN) have been removed altogether as they are no longer considered standard of care. Previous versions of the Guidelines (e.g. v.8.2) with details on IFN/RBV can, however, still be found online (www.eacsociety.org/guidelines/guidelines-archive/archive.html) [6]. Treatment for HCV with direct-acting antivirals (DAAs) should be considered for everyone coinfected with HIV regardless of fibrosis stage, and the treatment section has been updated to include information on the latest approved pangenotypic drugs vosevi (combination of sofosbuvir, velpatasvir and voxilaprevir) and maviret (glecaprevir and pibrentasvir) recommended (Table 2). Use of boceprevir and telaprevir is no longer recommended because of high rates of adverse drug reactions and insufficient cure rates.

The table of drug–drug interactions between individual DAAs and antiretrovirals has also been updated with the newest drugs and remains important because of the potentially deleterious interactions between DAAs and certain boosted PIs or NNRTIs.

Recommendations for DAA treatment failure management have been further extended to include specifications of possible drug combinations, treatment duration and resistance testing.

The algorithm for management of acute HCV infection has been revised with a focus on risk reduction, treatment of concomitant sexually transmitted infections and considerations of short DAA treatment and enrollment in clinical trials.

As the optimal treatment duration for HBV infection remains unknown, current expert opinion suggests lifelong treatment.

Added to the 2017 version are also recommendations to include TDF or TAF for all HBV surface antigen (HBsAg)-positive coinfected persons treated with chemotherapy or other immunosuppressive therapies. Similarly, all anti-HBC-positive persons treated with severe immunosuppressive therapies should be treated with TDF/TAF-containing ART to prevent HBV reactivation.

Opportunistic diseases section
Based on the findings of the REALITY trial [7], which was performed in sub-Saharan African countries, recommendations on enhanced infection prophylaxis in severely immunosuppressed individuals (CD4 count < 50 cells/μL) with isoniazid for 12 weeks, fluconazole 100 mg/day for 12 weeks, azithromycin 500 mg/day for 5 days and a single dose of albenozole 400 mg in addition to trimethoprim/sulfamethoxazole have been added to decrease risks of all opportunistic infections, including cryptococcal meningitis, and mortality. In countries where flucytosine is not available, fluconazole 400 mg
twice a day (bid) has been added as a possible alternative in combination with liposomal amphotericin B during the induction phase for cryptococcal meningitis.

In the section on tuberculosis (TB) management, it is underlined that intermittent TB treatment (i.e. two to three times weekly) is contraindicated in HIV-positive persons.

A recommendation has been added to consider supplementary steroid therapy to prevent IRIS in individuals treated for active TB starting ART [8].

For resistant (MDR/XDR) TB, preliminary data from the Nix trail [9] suggest that using a three-drug combination (pretomanid, bedaquiline and linezolid) may be as effective as a five-drug regimen, and may reduce treatment duration from 18–24 to 6–10 months.

In persons with latent TB, a 9-month treatment duration with isoniazid is recommended in countries with a high TB prevalence. For treating resistant latent TB, regimens have to be chosen on an individual basis.

Among the preferred treatment options for cerebral toxoplasmosis, intravenous trimethoprim/sulfamethoxazole has been added as a treatment option when oral administration is not possible.

Conclusions

The revised v.9.0 of the EACS Guidelines has been updated in collaboration with a large team of HIV and external experts and is available online, as a free app, and as a booklet. The 2017 version provides a holistic approach to HIV care, aims to cover a diverse geographical area and is translated into Spanish, Portuguese, French, Russian, German and Chinese.
Appendix 1

Panel members

The EACS Medical Secretariat is responsible for the coordination and updating of the EACS Guidelines based on the recommendations from the four EACS panels.

Guidelines Chair and Coordinator: Manuel Battegay, Basel, Switzerland.
Assistant Coordinator: Lene Ryom, Copenhagen, Denmark.

HIV treatment

Chair: Anton Pozniak, London, UK.
Vice-Chair: José Arribas, Madrid, Spain.
Young Scientist: Margherita Bracchi, London, UK.
Panel members: Antonella d’Arminio Monforte, Milan, Italy; Manuel Battegay, Basel, Switzerland; Nathan Clumeck, Brussels, Belgium; Nikos Dedes, Athens, Greece; José M. Gatell, Barcelona, Spain; Andrzej Horban, Warsaw, Poland; Christine Katlama, Paris, France; Jens D. Lundgren, Copenhagen, Denmark; Sheena McCormack, London, UK; Jean-Michel Molina, Paris, France; Cristina Mussini, Modena, Italy; François Raffi, Nantes, France; Peter Reiss, Amsterdam, the Netherlands; Hans-Jürgen Stellbrink, Hamburg, Germany.

Comorbidities

Chair: Georg Behrens, Hannover, Germany.
Vice-Chair: Patrick Mallon, Dublin, Ireland.
Young scientist: Lene Ryom, Copenhagen, Denmark.
Panel members: Manuel Battegay, Basel, Switzerland; Mark Bower, London, UK; Paola Cinque, Milan, Italy; Simon Collins, London, UK; Juliet Compston, Cambridge, UK; Stéphane De Wit, Brussels, Belgium; Leonardo M. Fabbri, Modena, Italy; Christoph A. Fux, Aarau, Switzerland; Giovanni Guaraldi, Modena, Italy; Jens D. Lundgren, Copenhagen, Denmark; Esteban Martínez, Barcelona, Spain; Catia Marzolini, Basel, Switzerland; Socrates Papapoulos, Leiden, the Netherlands; Renaud du Pasquier, Lausanne, Switzerland; Neil Poulter, London, UK; Peter Reiss, Amsterdam, the Netherlands; Ian Williams, London, UK; Alan Winston, London, UK.

Coinfections

Chair: Massimo Puoti, Milan, Italy.

Vice-Chair: Andri Rauch, Bern, Switzerland.
Young scientist: Christoph Boesecke, Bonn, Germany.
Panel members: Juan Berenguer, Madrid, Spain; Sanjay Bhagani, London, UK; Raffaele Bruno, Pavia, Italy; Svilen Konov, London, UK; Karine Lacombe, Paris, France; Stefan Mauss, Düsseldorf, Germany; Luis Mendão, Lisbon, Portugal; Lars Peters, Copenhagen, Denmark; Jürgen K. Rockstroh, Bonn, Germany.

Opportunistic infections

Chair: José M. Miro, Barcelona, Spain.
Vice-Chair: Ole Kirk, Copenhagen, Denmark.
Young scientist: Juan Ambrosioni, Barcelona, Spain.
Panel members: Paola Cinque, Milan, Italy; Gerd Fatkenheuer, Cologne, Germany; Hansjakob Furrer, Bern, Switzerland; Amanda Mocroft, London, UK; Philippe Morlat, Bordeaux, France; Anton Pozniak, London, UK; Alain Volny-Anne; Paris, France.

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