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Part IV Prevention and Management of Co-morbidities in PLWH

Prof. Patrick Mallon
for the EACS Co-morbidities Guidelines panel

Disclosure Information

Speaker Bureau / Honoraria:
ViiV Healthcare, Merck Sharpe and Dohme, Gilead Sciences, Janssen Cilag (Tibotec), Bristol Myers Squibb

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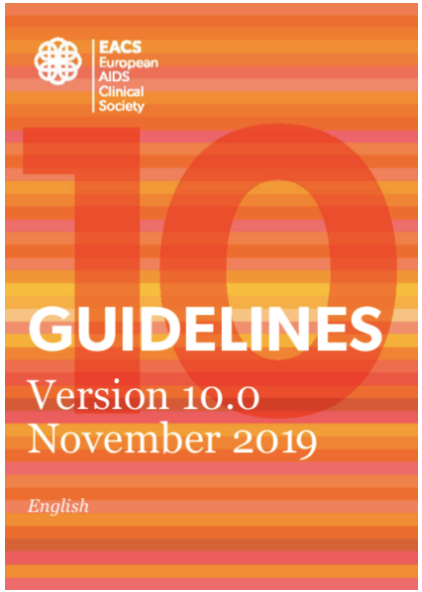
NIH
Wellcome Trust
Health Research Board (Ireland)
Enterprise Ireland

Co-morbidities Guidelines V10

- 44 pages in length
- 42 sections (12 online)
- 12 groups of conditions



- Bone diseases
- Cardiovascular diseases
- Diabetes mellitus
- Frailty
- Immunosuppression & Transplantation
- Liver disease & Cirrhosis
- Mental health
- Metabolic diseases (inc. Obesity)
- Neurocognitive function
- Renal disease
- Sexual and Reproductive Health
- Travel & Vaccination

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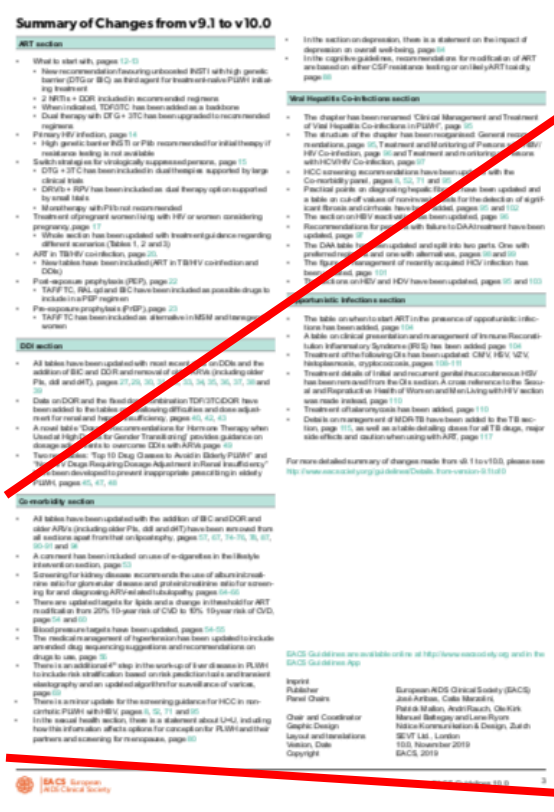
Co-morbidities Guidelines V10


Summary of Changes from v9.1 to v10.0

ART section

- What to start with, pages 12-13
  - New recommendation favouring unboosted INSTI with high genetic barrier (DTG or BIC) as third agent for treatment-naive PLWH initiating treatment
  - 2 NRTIs + DOR included in recommended regimens
  - When indicated, TDF/3TC has been added as a backbone
  - Dual therapy with DTG + 3TC has been upgraded to recommended regimens
- Primary HIV infection, page 14
  - High genetic barrier INSTI or PIb recommended for initial therapy if resistance testing is not available
- Switch strategies for virologically suppressed persons, page 15
  - DTG + 3TC has been included in dual therapies supported by large clinical trials
  - DRVb + RPV has been included as dual therapy option supported by small trials
  - Monotherapy with PIb not recommended
- Treatment of pregnant women living with HIV or women considering pregnancy, page 17
  - Whole section has been updated with treatment guidance regarding different scenarios (Tables 1, 2 and 3)
- ART in TB/HIV co-infection, page 25
  - New tables have been included (ART in TB/HIV co-infection and DDIs)
- Post-exposure prophylaxis (PEP), page 22
  - TAF/FTC, RAL-qd and BIC have been included as possible drugs to include in a PEP regimen
- Pre-exposure prophylaxis (PrEP), page 23
  - TAF/FTC has been included as alternative in MSM and transgender women

DDI section

- All tables have been updated with most recent information on DDIs and the addition of BIC and DOR and removal of older ARVs (including older PIs, ddI and d4T), pages 27, 28, 30, 31, 32, 33, 34, 35, 36, 37, 38 and 39
- Data on DOR and the fixed-dose combination TDF/3TC/DOR have been added to the tables and the following difficulties and dose adjustment for renal and hepatic insufficiency, pages 40, 42, 43
- A novel table "Drug Interactions for Hormone Therapy when Used at High Doses for Gender Transitioning" provides guidance on dosage adjustments to overcome DDIs with ARVs page 49
- Two new tables "Top 10 Drug Classes to Avoid in Elderly PLWH" and "Top 10 Drugs Requiring Dosage Adjustment in Renal Insufficiency" have been developed to prevent inappropriate prescribing in elderly PLWH, pages 45, 47, 48

Co-morbidity section

- All tables have been updated with the addition of BIC and DOR and older ARVs (including older PIs, ddI and d4T) have been removed from all sections apart from that on lipoatrophy, pages 57, 67, 74-76, 78, 87, 90-91 and 94
- A comment has been included on use of e-cigarettes in the lifestyle intervention section, page 53
- Screening for kidney disease recommends the use of albumin/creatinine ratio for glomerular disease and protein/creatinine ratio for screening for and diagnosing ARV-related tubulopathy, pages 64-66
- There are updated targets for lipids and a change in threshold for ART modification from 20% 10-year risk of CVD to 10% 10-year risk of CVD, page 54 and 60
- Blood pressure targets have been updated, pages 54-55
- The medical management of hypertension has been updated to include amended drug sequencing suggestions and recommendations on drugs to use, page 56
- There is an additional 4th step in the work-up of liver disease in PLWH to include risk stratification based on risk prediction tools and transient elastography and an updated algorithm for surveillance of varices, page 69
- There is a minor update for the screening guidance for HCC in non-cirrhotic PLWH with HBV, pages 8, 52, 71 and 95
- In the sexual health section, there is a statement about U=U, including how this information affects options for conception for PLWH and their partners and screening for menopause, page 80
- In the section on depression, there is a statement on the impact of depression on overall well-being, page 84
- In the cognitive guidelines, recommendations for modification of ART are based on either CSF resistance testing or on likely ART toxicity, page 88

Viral Hepatitis Co-infections section

- The chapter has been renamed 'Clinical Management and Treatment of Viral Hepatitis Co-infections in PLWH', page 95
- The structure of the chapter has been reorganised. General recommendations, page 95, Treatment and Monitoring of Persons with HBV/HIV Co-infection, page 96 and Treatment and monitoring of persons with HCV/HIV Co-infection, page 97
- HCC screening recommendations have been updated with the Co-morbidity panel, pages 8, 52, 71 and 95
- Practical points on diagnosing hepatic fibrosis have been updated and a table on cut-off values of noninvasive methods for the detection of significant fibrosis and cirrhosis have been added, pages 98 and 102
- The section on HBV exacerbations has been updated, page 96
- Recommendations for persons with failure to DAA treatment have been updated, page 97
- The DAA table has been updated and split into two parts. One with preferred regimens and one with alternatives, pages 98 and 99
- The flowchart on management of recently acquired HCV infection has been updated, page 100
- The sections on HDV and HDV have been updated, pages 95 and 103

Opportunistic infections section

- The table on when to start ART in the presence of opportunistic infections has been added, page 104
- A table on clinical presentation and management of Immune Reconstitution Inflammatory Syndrome (IRIS) has been added page 104
- Treatment of the following OIs has been updated: CMV, HSV, VZV, histoplasmosis, cryptococcosis, pages 108-110
- Treatment details of Initial and recurrent genital mucocutaneous HSV has been removed from the OIs section. A cross-reference to the Sexual and Reproductive Health of Women and Men Living with HIV section was made instead, page 110
- Treatment of talaromycosis has been added, page 110
- Details on management of MDR-TB have been added to the TB section, page 111, as well as a table detailing doses for all TB drugs, major side effects and caution when using with ART, page 117

For more detailed summary of changes made from v9.1 to v10.0, please see http://www.eacsociety.org/guidelines/Details_from-version-9.1to10

EACS Guidelines are available online at http://www.eacsociety.org and in the EACS Guidelines App

Imprint

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Hypertension

Hypertension: Diagnosis, Grading and Management

Other risk factors, asymptomatic organ damage or disease	Blood pressure (mmHg)	Blood pressure (mmHg)	Blood pressure (mmHg)	Blood pressure (mmHg)
	High normal SBP 130-139 or DBP 85-89	Grade 1 hypertension SBP 140-159 or DBP 90-99	Grade 2 hypertension SBP 160-179 or DBP 100-109	Grade 3 hypertension SBP ≥ 180 or DBP ≥ 110
No other risk factors	• Lifestyle changes[i] • No BP drug intervention	• Lifestyle changes[i] for several months • Then add BP drugs targeting < 130/80[ii]	• Lifestyle changes[i] for several weeks • Then add BP drugs targeting < 130/80[ii]	• Lifestyle changes[i] • Immediate BP drugs targeting < 130/80[ii]
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Organ damage, CKD stage 3 or diabetes	• Lifestyle changes[i] • Consider blood pressure drugs targeting < 130/80[ii]	• Lifestyle changes[i] • BP drugs targeting < 130/80[ii]	• Lifestyle changes[i] • BP drugs targeting < 130/80[ii]	• Lifestyle changes[i] • Immediate BP drugs targeting < 130/80[ii]
Symptomatic CVD, CKD stage ≥ 4 or diabetes with organ damage/risk factors	• Lifestyle changes[i] • Consider blood pressure drugs targeting < 130/80[ii]	• Lifestyle changes[i] • BP drugs targeting < 130/80[ii]	• Lifestyle changes[i] • BP drugs targeting < 130/80[ii]	• Lifestyle changes[i] • Immediate BP drugs targeting < 130/80[ii]

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Hypertension - management

Choosing drugs[i] for persons newly diagnosed with hypertension

< 55 years	≥ 55 years or black[ii] person of any age
A[iii]	C[iii,iv]
↓	↓
A + C*[iii] (white person) :	A + C or C + D[ii] (black person)
↓	
A + C + D[iii]	
↓	
A + C + D[iii] + Spirolactone (12.5 to 50 mg)	

[v] Add a-blocker (e.g. doxazosin [slow release]) or β-blocker (e.g. bisoprolol). Refer to specialist.

A = ACE inhibitor
C = Dihydropyridine Calcium Channel Blocker
D = Thiazide-type diuretic

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10 GUIDELINES

Hypertension - management

Choosing drugs[(i)] for persons newly diagnosed with hypertension

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↓	
A + C + D[(iii)]	

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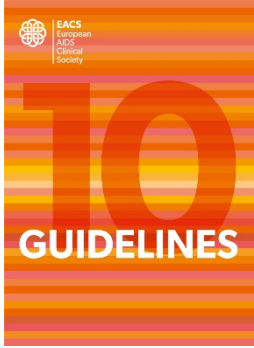
Cardiovascular Disease prevention



Assess CVD risk in next 10 years[i]

↓

Advise on diet and lifestyle in all persons

Consider ART modification if 10-year CVD risk ≥ 10%[ii]

↓

Smoking (see page 53) → Identify key modifiable risk factors[iii]

Blood pressure

↓

Drug treatment if: SBP ≥ 140 or DBP ≥ 90 mmHg (especially if 10-year CVD risk ≥ 10%)

↓

Target[v]

SBP < 130 mmHg

DBP < 80 mmHg

↓

Treatment (see page 55-57)

Coagulation

↓

Drug treatment if: established CVD only

↓

Target - N/A

↓

Consider treating with acetylsalicylic acid 75-150 mg[vii]

Glucose

↓

Confirm DM and treat with diet and drugs

↓

Target

HbA1C 6.5-7.0%

↓

Treatment (see page 59)

Lipids

↓

Drug treatment[iv] if: established CVD or type 2 diabetes or 10-year CVD risk ≥ 10%

↓

Target*

	2ry prevention or very high risk	1ry Prevention
LDL**	< 1.4 (55)	< 2.0 (80)
Non LDL	< 2.2 (85)	< 3.0 (115)

↓

Treatment (see page 60)

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Cardiovascular Disease prevention

Assess CVD risk in next 10 years[i]

Advise on diet and lifestyle in all persons

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Blood pressure

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Target[v]

SBP < 130 mmHg

DBP < 80 mmHg

Treatment (see page 55-57)

Coagulation

Drug treatment if: established CVD only

Target - N/A

Consider treating with acetylsalicylic acid 75-150 mg[vii]

Glucose

Confirm DM and treat with diet and drugs

Target

HbA1C 6.5-7.0%

Treatment (see page 59)

Lipids

Drug treatment[iv] if: established CVD or type 2 diabetes or 10-year CVD risk ≥ 10%

Target*

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Treatment (see page 60)

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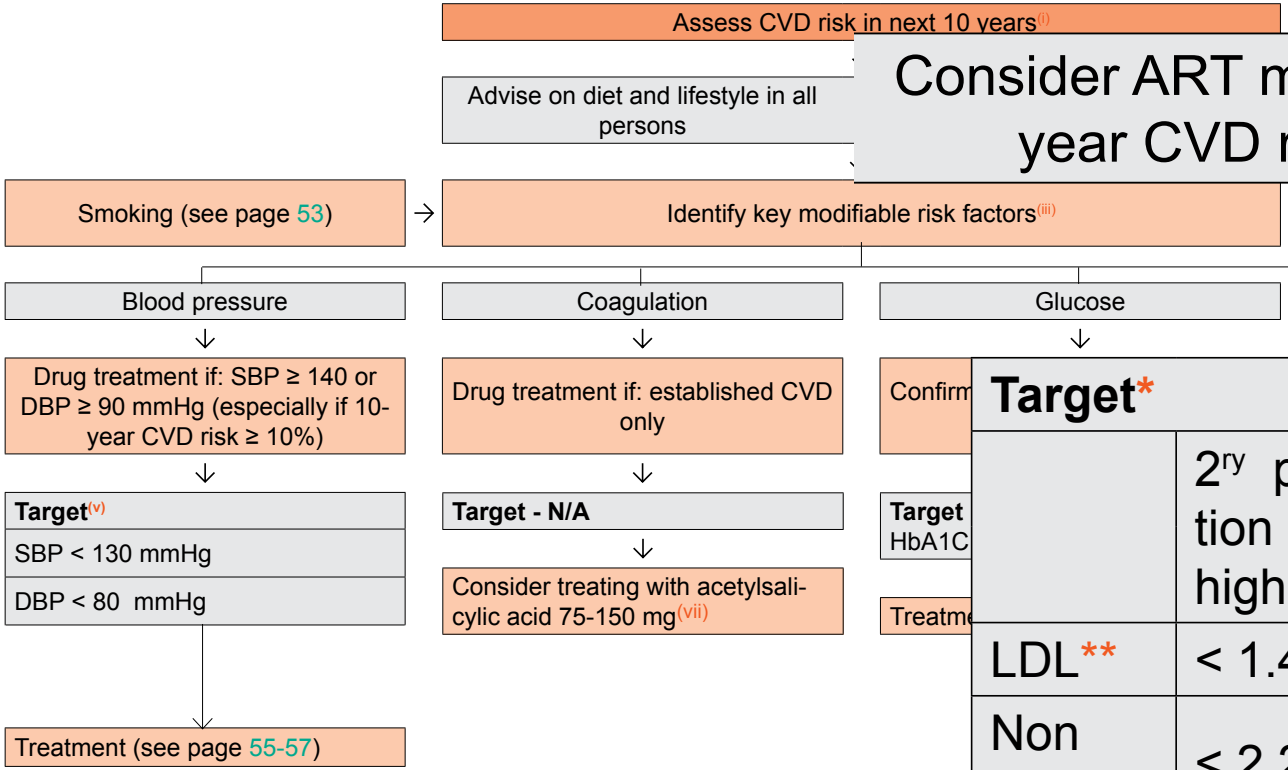
Cardiovascular Disease prevention



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Kidney Disease

Kidney Disease: Definition, Diagnosis and Management

Diagnosis of kidney disease

		eGFR[i]			
		> 60 mL/min	**> 60 mL/min, but accelerated decline of eGFR***	**> 30 - ≤ 60 mL/min**	**≤ 30 mL/min**
Proteinuria (mg/mmol)[ii]	UA/C[iii] < 3	Regular follow-up			• Check risk factors for CKD and nephrotoxic medicines including ART[iv] • Discontinue or adjust drug dosages where appropriate[v] • Perform renal ultrasound • Urgent referral to nephrologist
	UA/C[iii] 3-30	• Check risk factors for CKD[x] and nephrotoxic medicines including ART[iv, x] • Discontinue or adjust drug dosages where appropriate[v] • Perform renal ultrasound • If haematuria present with any level of proteinuria refer to nephrologist • Refer to nephrologist if new CKD or progressive decline in eGFR			
	UA/C[iii] > 30				

Kidney Disease

Kidney Disease: Definition, Diagnosis and Management

Proteinuria (mg/mmol)[ii]		> 60 mL/min, but accelerated decline of eGFR*	> 30 - ≤ 60 mL/ min	≤ 30 mL/min
	UA/C[iii] < 3			
	UA/C[iii] 3-30	up ctors for CKD[x] and nephrotoxic luding ART[iv, x] r adjust drug dosages where ultrasound present with any level of proteinu- phrologist rologist if new CKD or progressive FR		• Check risk factors for CKD and nephrotoxic medicines including ART[iv] • Discontinue or adjust drug dosages where appropriate[v] • Perform renal ultrasound • Urgent referral to nephrologist
	UA/C[iii] > 30			

Kidney Disease

Indications and Tests for Proximal Renal Tubulopathy (PRT)

Indications for proximal renal tubulopathy tests	Proximal renal tubulopathy tests[iv], including	Replace TDF by non-tenofovir drug or TAF* alternative drug if:
• Progressive decline in eGFR[i] & eGFR ≤ 90 mL/min & no other cause and/or • Confirmed hypophosphataemia[ii] and/or • Confirmed increase in UP/C[iii] • Renal insufficiency even if stable (eGFR ≤ 60 mL/min) • Tubular proteinuria[v]	• Blood phosphate and urinary phosphate excretion[vi] • Blood glucose and glucosuria • Serum bicarbonate and urinary pH[vii] • Blood uric acid level and urinary uric acid excretion[viii] • Serum potassium and urinary potassium excretion	• Confirmed proximal renal tubulopathy with no other cause

Kidney Disease

Indications and Tests for Proximal Renal Tubulopathy (PRT)

Indications for proximal renal tubulopathy tests	Proximal renal tubulopathy tests[iv], including	Replace TDF by non-tenofovir drug or TAF* alternative drug if:
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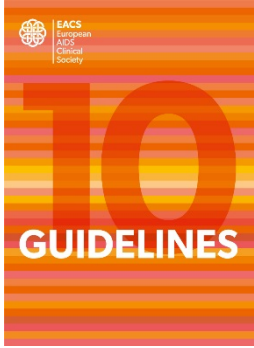
What about HIV and Ageing?



- Current guidelines cover a range of age-related conditions
- Comprehensive guidance on screening, prevention and management
- No agreed ‘old age’ cut-off
- Sections include age-specific guidance

New section – Frailty and Ageing

Feature	Frailty Phenotype	Frailty Index
Clinical definition	Based on presence of signs, symptoms (pre-disability syndrome)	Based on presence of diseases, disabilities (accumulation of deficits)
How to assess	Assessed by five specific features [22]: 1. self-reported weight loss (a) 2. self-reported exhaustion (b) 3. low levels of physical activity as measured by Minnesota Leisure physical activity questionnaire (c) 4. measured 4 m walk speed time (d) 5. measured grip strength (e)	A frailty index is calculated based on the number of health deficits out of > 30 assessed health deficits [23] Health variables, including signs and symptoms of disease, laboratory measures, and self-reported data Data routinely collected in medical records can be included if they characterise age-related, acquired health deficits which cover a range of physiologic systems
How to interpret	Categorical variables Total score of 5 items: 0 deficits = fit 1-2 deficits = pre-frail 3 + deficits = frail	Continuous variables Index ranges from 0 to 1: > 0.25 = fit 0.25 - 0.4 = frail > 0.4 = most frail
How to address frailty [24]	Promote Comprehensive Geriatric Assessment (CGA), aimed at personalising interventions according to benefits/priorities for a given person through a multidisciplinary diagnostic and treatment process, that identifies medical, psychosocial, and functional limitations aimed at maximising overall health with ageing and the improvement of quality of life	
Recommendations [25], [26]	In PLWH who are frail: 1. Sustain and recover physical function impairment and sarcopenia prescribing physical activity with a resistance training component 2. Address polypharmacy by reducing or deprescribing any inappropriate/superfluous medications, see Prescribing in Elderly PLWH 3. Screen for, and address modifiable causes of fatigue 4. For PLWH exhibiting unintentional weight loss, screen for reversible causes and consider food fortification and protein/caloric supplementation 5. Prescribe vitamin D for individuals deficient in vitamin D, see page 62	

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Promote Comprehensive Geriatric Assessment (CGA), aimed at personalising interventions according to benefits/priorities for a given person through a multidisciplinary diagnostic and treatment process, that identifies medical, psychosocial, and functional limitations aimed at maximising overall health with ageing and the improvement of quality of life

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What about obesity?

Obesity

Definition:
Body mass index (BMI) > 30 kg/m²
Also body fat > 25% (men) or > 33% (women) for persons with low muscle mass
Waist circumference is an indicator of abdominal fat and a useful predictor of cardiometabolic diseases. Cut-off points indicating higher cardiometabolic risks are > 88 cm for women and > 102 cm for men.Naturally, different ethnicities have different body builds and proportions. Asians have a naturally slimmer, petite frame and therefore the waist circumference cut off for Japanese, Chinese and South Asian people is lower than for Caucasians.
Visceral adipose tissue (VAT) area ≥ 130 cm² is a validated threshold for increased cardiometabolic risk
Consequences:
Not only cosmetic concern
Worse outcomes with surgery and actute infections (e.g. pneumonia, influenza)
Increased risk of diabetes mellitus, hypertension, cardiovascular disease, some cancers, obstructive sleep apnea, colelithiasis, erectile dysfunction, non-alcoholic fatty liver disease, ostheoarthritis and depression
Contributing factors:
Older age
Sedentary lifestyle
Intake of excess or poor quality calories (e.g. saturated fats, processed sugars)
Excess alcohol consumption
Some medications (e.g. psychotropic drugs, steroids, antidiabetci drugs)
Endocrine disorders (e.g. GH deficiency, hypothyroidism, Cushing's syndrome, hypogonadism)
Assessment:
Weight, waist circumference and BMI, see page 53
Fasting lipids and glucose, see pages 54, 58 and 60
Dyslipidaemia management, see page 60
Assess NAFLD, see page 72
Prevention of cardiovascular disease, see page 54
Aim:
An objective of 5% weight loss from initial weight may have a beneficial impact on obesity-related comorbidities
Management:
Structured exercise
Dietary intervention
No data on ART switch
Treat underlying or associated conditions
There are several drugs approved to treat obesity (e.g. orlistat, phentermine/topiramate, lorcaserin, nalterxone/bupropion, liraglutide) but they should be prescribed by an endocrinologist or obesity expert. All of them may have adverse effects and drug-drug interactions with ART.
Bariatric surgery may be considered in persons with a BMI ≥ 40 kg/m² or ≥ 35 kg/m² with obesity-related comorbidities refractory to serious attempts at lifestyle changes and should be coordinated through an established, specialist led obesity programme. Consider theraputic drug monitoring and drug dose adjustment post-bariatric surgery
Surgery can be considered for localised lipomas and dorsocervical fat accumulation for cosmetic purposes only

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Body mass index (BMI) > 30 kg/m²
Also body fat > 25% (men) or > 33% (women) for persons with low muscle mass
Waist circumference is an indicator of abdominal fat and a useful predictor of cardiometabolic diseases. Cut-off points indicating higher cardiometabolic risks are > 88 cm for women and > 102 cm for men.Naturally, different ethnicities have different body builds and proportions. Asians have a naturally slimmer, petite frame and therefore the waist circumference cut off for Japanese, Chinese and South Asian people is lower than for Caucasians.
Visceral adipose tissue (VAT) area ≥ 130 cm² is a validated threshold for increased cardiometabolic risk
Consequences:
Not only cosmetic concern
Worse outcomes with surgery and actute infections (e.g. pneumonia, influenza)
Increased risk of diabetes mellitus, hypertension, cardiovascular disease, some cancers, obstructive sleep apnea, colelithiasis, erectile dysfunction, non-alco-

- Rapidly evolving field
- Will continue to update
- No ART-specific recommendations

Prevention of cardiovascular disease, see page 34
Aim:
An objective of 5% weight loss from initial weight may have a beneficial impact on obesity-related comorbidities
Management:
Structured exercise
Dietary intervention
No data on ART switch
Treat underlying or associated conditions
There are several drugs approved to treat obesity (e.g. orlistat, phentermine/topiramate, lorcaserin, nalterxone/bupropion, liraglutide) but they should be prescribed by an endocrinologist or obesity expert. All of them may have adverse effects and drug-drug interactions with ART.
Bariatric surgery may be considered in persons with a BMI ≥ 40 kg/m² or ≥ 35 kg/m² with obesity-related comorbidities refractory to serious attempts at lifestyle changes and should be coordinated through an established, specialist led obesity programme. Consider theraputic drug monitoring and drug dose adjustment post-bariatric surgery
Surgery can be considered for localised lipomas and dorsocervical fat accumulation for cosmetic purposes only

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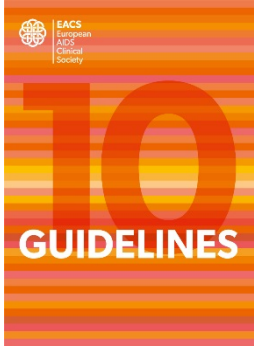
10
GUIDELINES

What about obesity?

Obesity

	Skin	Digestive	Liver	CV	Musculo-skeletal	Genito-urinary	Nervous	Body fat	Metabolic	Other
NRTIs										
TAF[iii]									**Weight increase**	
INSTI										
RAL		Nausea			Myopathy, Rhabdomy-olysis		Sleep disturbance, Headache			Systemic hypersensitivity syndrome[viii] **Weight increase**
DTG	Rash	Nausea				↓ eGFR[iv]	**Sleep disturbance, Headache**			Systemic hypersensitivity syndrome (< 1%) **Weight increase**
EVG/c		**Nausea,** Diarrhoea				↓ **eGFR**[iv]	Sleep disturbance, Headache			**Weight increase**
BIC						↓ eGFR[iv]	Sleep disturbance, Headache			**Weight increase**

Acknowledgements



EACS panel members

Chair: Patrick Mallon	**Dublin, Ireland**
Vice chair: Alan Winston	**London, UK**
Young Scientist: Aoife Cotter	**Dublin, Ireland**
Manuel Battegay	Basel, Switzerland
Georg Behrens	Hanover, Germany
Mark Bower	London, UK
Paola Cinque	Milan, Italy
Simon Collins	London, UK
Juliet Compston	Cambridge, UK
Stéphane De Wit	Brussels, Belgium
Leonardo Fabbri	Modena, Italy
Christoph Fux	Aarau, Switzerland
Magnus Gisslen	Gothenburg, Sweden
Giovanni Guaraldi	Modena, Italy
Justyna Kowalska	Warsaw, Poland
Jens Lundgren	Copenhagen, Denmark
Esteban Martinez	Barcelona, Spain
Catia Marzolini	Basel, Switzerland
José Miro	Barcelona, Spain
Eugenia Negredo	Barcelona, Spain
Neil Poulter	London, UK
Peter Reiss	Amsterdam, The Netherlands
Lene Ryom	Copenhagen, Denmark
Giada Sebastiani	Montreal, Canada

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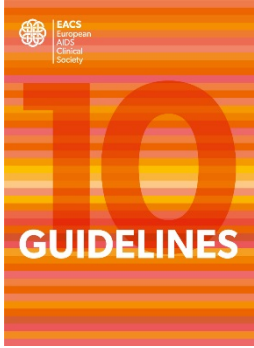
Guidelines Chair: **Manuel Battegay**
Guidelines Coordinator: **Lene Ryom**

Title

Text



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