Learning Activity & Audit Program

Welcome

The THRIVE Program is a continuing professional development learning activity and patient audit designed to assist you to implement a standardised process for the medical monitoring aspects of both newly diagnosed and treatment experienced people living with HIV (PLWHIV) based on guidance from the ASHM Monitoring Tool. This module will focus on specific aspects of monitoring including:

- drug interactions.

The THRIVE Program consists of:

Learning activity: Pre-requisite review of learning material and professional reflection contained in this module prior to undertaking the patient audit.

Patient audit: Audit of 5 patients from your practice utilising the HIV Monitoring Tool framework.



BASELINE ASSESSMENT

 Medical co-morbidities such as co-infections, cardiovascular disease, diabetes mellitus, neurological disease, renal impairment, osteoporosis, depression and cognitive decline

• Antiretroviral therapy (ART)-related factors such as adherence, adverse effects and

An RACGP CPD Accredited Activity (ID:223405) 40 CPD Program points allocated

ASHM HIV CPD Accredited Activity 6 HIV CPD points awarded

> **ONGOING** REVIEW







Program learning objectives

- PLWHIV in your clinical practice.
- and/or treatment-experienced patients.



1. Review current approach to monitoring and identification of clinical issues requiring further management, in relation to co-morbidities and antiretroviral therapy (ART) in

2. Evaluate a minimum of 5 PLWHIV against the patient audit framework provided (patient review form), based on the recommendations of the ASHM Monitoring Tool.

3. Integrate a standard process to optimise medical monitoring and management of PLWHIV into your clinical practice by identifying follow-up actions in newly diagnosed



Professional reflection

1. Approximately what proportion of your PLWHIV on ART do you think have other co-infections or physical co-morbidities (cardiovascular, dyslipidaemia, renal, liver, bone, cognitive, psychiatric)?

<10%

- 11-20%
- 21-30%
- 31-40%
- 41–50%
- >50%
- **2.** How frequently do you currently perform ongoing review of your PLWHIV for co-morbidities or risk of co-morbidities?

Approx. every 3–6 months (at each review visit)

As per the ASHM Monitoring Tool schedule

Approx. once per year

Never

Other

3. What are the co-morbidities you are currently aware of that may impact selection of ART?

4. Do you review ART in PLWHIV when co-morbidities develop or they become at risk of developing co-morbidities?

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REVIEW

- **5.** How frequently do you currently review your PLWHIV for addition of new medications and potential drug interactions?
 - Approx. every 3–6 months (at each review visit)
 - As per the ASHM Monitoring Tool schedule
 - Approx. once per year
 - Never
 - Other



Introduction

Effective utilisation of ART requires a comprehensive initial assessment and ongoing patient monitoring to address:1

- Therapeutic response
- Adverse effects
- Co-morbidities
- Co-infections
- Drug interactions
- Lifestyle factors
- Adherence.

The ASHM HIV Monitoring Tool has been developed to help improve the quality and safety of ART prescribing in Australian general practice, with the purpose of assisting HIV S100 prescribers with decision making when conducting an initial assessment and ongoing monitoring following HIV diagnosis.¹

HISTORY	EXAMINATION	ASSESSM
HIV • Date of exposure or testing history • Partner status • Contact tracing Medical • Co-morbidities • Baview medicines	 Vital signs (blood pressure, pulse, temperature) Height, weight, body mass index, waist circumference General examination Brief mental state exam if indicated (see Box 2) 	 Immune deficiency Physical co-morbid Co-infections Depression or psyc (see Box 2)
Allergies Family history (premature cardiovascular disease, renal, diabetes mellitus) Vaccination history	Check for signs of immune deficiency (see Box 1)	Box 2: Depression S and Cognitive Funct Depression Screening Answering "yes" to eithe
Lifestyle • Drug and alcohol use • Smoking Diet and exercise • Sexual health	Box 1: Stages of HIV infection • Acute infection: (in 70% of patients) fever, rash, lymphadenopathy, pharyngitis, myalgia, diarthoea, about 2 weeks after exposure • Asymptomatic infection: for several years following infection • Immune deficiency: multiple symptoms related to declining CD4 T-cell count such as oral thrush, diarthoea, weight loss, skin infections, herpes zoster • AIDS: opportunistic infections such as poptrunsize infections acus as poptruns and acute as a several part of the symptome and acus as a several symptome and acute as a several symptome and acute as a several symptome and acutes such as faposi's sarcoma'	suggest depression. Ov how often have you bev following problems? 1. Little interest or plea 2. Feeling down, depre Cognitive function ? Answering 'yes' to one- may suggest the preser 1. Do you experience fre you forget special eve 2. Do you feel that you. planning activities or 3. Do you have difficult (e.g. to a conversatio
Independent. Not-for-profit. Evidence-based. www.nps.org.au NPS MedicineWise commissioned ASHM to independently develop this resource for its Quality use of ART for people living with HIV education program. The program was funded by an unconditional independent medical education grant from Gilead Sciences PV Ltd	References 1. EACS, European AIDS Clinical Society Guidelines, October 2018 2. Maurer, D. Screening for Depression, American Family Physician, January 2012 3. AUDSinfo, DHHS Guidelines for the Prevention and Treatment of Opportunistic Infections in HV-Infected Adults and Adolescents, August 2019 4. ASHM, US DHHS Antiretroviral Guidelines with Australian Componence August 2019	 RACGP, Guidelines for Preve Practice, 9th Edition 2018 ASHA, Australian STI Manage ATAGI Australian Immunisat Government Department of Cancer Council Australia, Na Program Guidelines, August ASHM, Anal Cancer in Men I

BASELINE ASSESSMENT



ONGOING REVIEW



Baseline assessment in a person newly diagnosed with HIV



Every patient diagnosed with HIV should have a complete medical history, physical examination, laboratory evaluation and counselling regarding the implications of HIV infection.^{1,3}

The goals of the initial evaluation are to:^{2–4}

- Confirm the diagnosis of HIV infection
- Obtain appropriate history and baseline laboratory data
- Ensure patient understanding about HIV infection and transmission
- Initiate care as per recommended guidelines.

A comprehensive patient history should be obtained on initial assessment, including:

- and contact tracing
- Medical: pre-existing co-morbidities including psychiatric, co-infections, current medications, allergies, family history of cardiovascular disease, renal disease, diabetes, or cancer
- Lifestyle factors: smoking, diet and exercise, drug and alcohol use, and sexual health.

BASELINE ASSESSMENT

Examination

Assessment

Plan

- Patients living with HIV infection may experience many social, psychiatric, and medical issues that are best addressed through a patient-centred, multi-disciplinary approach.
- **HIV-related history:** date of exposure and testing history, partner status,

ONGOING REVIEW



Baseline assessment in a person newly diagnosed with HIV

History



Physical examination should include:¹

- Vital signs: e.g. pulse, blood pressure
- General appearance: height, weight, evidence of obesity (body mass index, waist circumference), wasting, or lipodystrophy
- General examination: cardiovascular, respiratory, abdominal examination, lymph nodes, opthalmology, oral, skin, and genital (if appropriate).

A brief mental state examination should be performed if there are any concerns about cognitive function.¹

Answering "yes" to one of cognitive disorders:¹

 Do you experience fre or appointments)?

- Do you feel that you are slower when reasoning, planning activities, or solving problems?
- Do you have difficulties paying attention (e.g. to a conversation, book, or movie)?



- Answering "yes" to one or more of these questions may suggest the presence
- Do you experience frequent memory loss (e.g. do you forget special events



Baseline assessment in a person newly diagnosed with HIV

History

Based on history and examination, the 'Assessment' phase considers the following patient aspects:¹

- Immune deficiency
- Physical co-morbidities
- Co-infections
- Depression or psychological problems.



Immune Deficiency - check for signs based on stage of HIV infection:

• Acute infection (in 70% of patients): fever, rash, lymphadenopathy, pharyngitis, myalgia, diarrhoea, approximately two weeks after exposure

• Asymptomatic infection: for several years following infection

• Immune deficiency: multiple symptoms relating to declining CD4 T-cell count e.g. oral thrush, diarrhoea, weight loss, skin infections, herpes zoster

• AIDS: opportunistic infections e.g. *Pneumocystis jiroveci* pneumonia (PJP), oesophageal candidiasis, cerebral toxoplasmosis, and cancers e.g. Kaposi's sarcoma.

N	



Baseline assessment in a person newly diagnosed with HIV

History

Physical co-morbidities

Patients should be assessed to identify any existing co-morbidities, or the risk of developing co-morbidities, including specific investigations as follows:¹

- Full blood count
- Fasting blood glucose
- Liver function tests

Additional assessments for determining the presence or risk of co-morbidities include:

- Cancer screening as per RACGP guidelines.





• Fasting lipids including TC, LDL-C, HDL and TG

• Renal: eGFR, urinalysis, protein/creatinine ratio

• Bone: calcium, phosphate, alkaline phosphatase, 25(OH) vitamin D.

Absolute CV risk check (<u>www.cvdcheck.org.au</u>)

• FRAX score (see www.sheffield.ac.uk/FRAX/tool.aspx)

ONGOING REVIEW



Baseline assessment in a person newly diagnosed with HIV

History

Co-infections

The following laboratory tests performed during initial patient visits are used to determine the presence and/or risk of co-infections:^{1,3}

- opportunistic infections¹
- Sexually transmitted infections (STIs)

Vaccinations should be confirmed or administered for relevant co-infections as needed (Refer HIV Monitoring Tool):¹ It is important to note that live vaccinations should not be given to patients who are immunosuppressed (CD4 count <200 cells/mm³).⁵



• The CD4 count is the most important laboratory indicator of immune function in people with HIV, and the strongest predictor of subsequent disease progression and survival according to findings from multiple clinical trials and cohort studies.³ The CD4 count should be measured in all patients at entry into care. It is the key factor in determining the need to initiate prophylaxis for opportunistic infections (OI) and in assessing the urgency of initiating ART. If CD4 count is <200 cells/mm³ consider immediate prophylaxis for

Tuberculosis CXR/Interferon Gamma Release Assay (IGRA) if high TB risk

• Viral hepatitis – hepatitis A, B and C serology

Serology for measles, mumps, rubella, varicella, toxoplasmosis, and cytomegalovirus.



Baseline assessment in a person newly diagnosed with HIV

History

Depression/psychosocial problems

following problems?"

1. Little interest or pleasure in doing things

2. Feeling down, depressed, or hopeless

BASELINE ASSESSMENT



- Perform depression screening (PHQ-2)^{1,2} if indicated. Answering "yes" to either of the following questions may suggest depression:
- "Over the past two weeks, how often have you been bothered by any of the
- People who screen positive should be further evaluated (e.g. DASS or K10) to determine whether they meet criteria for a depressive disorder.⁶



Baseline assessment in a person newly diagnosed with HIV

History

In addition to the previous investigations the 'Plan' phase of management includes the following baseline investigations.

HIV investigations¹⁻⁴

- Plasma HIV RNA (viral load)
- the assay's limit of detection)
- CD4 count

- ART selection
- taking ABC.



• HIV antibody testing (if prior documentation is not available or if HIV RNA is below

Genotypic resistance testing (for patients who have HIV RNA levels) to help guide

• HLA-B*5701 allele genotyping should be performed before initiation of abacavir as this gene is linked to the occurrence of systemic hypersensitivity syndrome in people



Baseline assessment in a person newly diagnosed with HIV

History

Initiating ART

irrespective of CD4 counts.^{2–4}

including;

- Assessment of high-risk behaviours
- Substance abuse
- Social support and economic factors (e.g. unstable housing)
- Mental illness
- Co-morbidities

And other factors that are known to impair adherence to ART and increase the risk of HIV transmission. Once identified, relevant factors should be managed accordingly.^{2–4}



- ART reduces HIV-related morbidity and mortality at all stages of
- HIV infection and has reduced HIV transmission.³ ART is recommended in all adult PLWHIV
- The initial evaluation should include discussion about the benefits of ART for the patient's health and to prevent ongoing HIV transmission. Newly-diagnosed people should also be asked about any prior use of antiretroviral agents for prevention of HIV infection.^{2,3}
- Baseline assessment should include an evaluation of the patient's readiness for ART,





Baseline assessment in a person newly diagnosed with HIV

History

Initiating ART (cont.)

Immediate (i.e. same day) start of ART should be considered, especially in the following situations:⁴





• The wish of a person living with HIV to start ART immediately

• In a setting where loss to follow-up is more likely if ART is not started the same day

• In the case of late presentation (CD4 count <350 cells/mm³) the initiation of ART should not be delayed, although a careful assessment for opportunistic infections must occur as it may not be safe to commence ART until further evaluation/management has occurred.

> **ONGOING** REVIEW



Baseline assessment in a person newly diagnosed with HIV

History

Clinical considerations when choosing an ART regimen

Selection of a regimen for a particular patient should be guided by a number of patientand drug-related factors with the goal of providing an effective, safe, tolerable, and easy to adhere to regimen in order to achieve sustained virological control.²

Pre-treatment viral load level is an important factor in the selection of an initial ART regimen because several currently approved ART drugs or regimens have been associated with poorer responses in those people with high baseline viral load.³

Drug-related factors

Drug-related factors include virologic efficacy, side effects, pill burden, dosing frequency, drug-drug and drug-food interaction potential, availability of fixed dose combination, access and cost.^{2,3}

> BASELINE **ASSESSMENT**

Examination

Assessment

Plan



REFERENCES

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REVIEW



Baseline assessment in a person newly diagnosed with HIV

History

hrive

Treatment Re-assessment

and HIV Evaluation

Patient-related factors

Patient-related factors^{2,3} include plasma HIV RNA (viral load), CD4 cell count, HIV resistance test results, HLA-B*5701 status, co-morbidities, concurrent medications, individual preferences, and anticipated adherence.

For specific guidance on recommended ART regimens for initial therapy in antiretroviral-naive patients, please refer to: <u>https://arv.ashm.org.au/</u> what-to-start-initial-combination-regimens-for-theantiretroviral-naive-patient/

> BASELINE **ASSESSMENT**

Examination Assessment Plan



REFERENCES

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Baseline assessment in a person newly diagnosed with HIV

History

Patient education and support

The plan must also include a discussion about reducing the risk of HIV transmission. Points to discuss include:

- Undetectable = Untransmittable (U=U)

This is particularly important in the setting of a detectable HIV viral load, where there is a high risk of HIV transmission.^{1,2}

Offer counselling and referral to a local PLWHIV service for peer support e.g. napwha.org.au/members.



Examination

Assessment



• Treatment as Prevention (TasP) and disclosure to sexual and/or needle-sharing partners.

ONGOING REVIEW



HIV Monitoring Tool: ongoing patient review

Patient history

- assessed at every visit.^{1,4}
- of the patient.^{1,4,6}
- HIV viral load for at least 6 months.

• Medicines – concomitant medicines, side effects, and adherence to medication should be

• It is important to re-evaluate the suitability of ART in light of any new medication the patient has been prescribed, relevant side effects and related conditions, and the impact on overall pill burden and adherence to ART.

Psychosocial – assess the ongoing social and welfare status and psychological wellbeing

 Sexual – review of sexual history should be undertaken every 6–12 months including. partner status, gender, STI risk/testing. Reinforce the importance of Treatment as Prevention (TasP) and maintaining an undetectable viral load to prevent transmission.^{1,3,4} Consider pre-exposure prophylaxis for partners if patient does not have an undetectable

 Lifestyle factors – ongoing monitoring of smoking, nutrition, alcohol and drug use, and levels of physical activity should be performed every 6-12 months with referral for counselling and treatment as required.^{1,4}





HIV Monitoring Tool: ongoing patient review

HIV investigations

Viral load is the most important indicator of initial and sustained response to ART and should be measured in all people with HIV at entry into care, at initiation of ART and on a regular basis thereafter.³

The following ongoing monitoring is recomended:¹

Assessment	Frequency
HIV viral load	Every 3–6 months
CD4 testing	Every 3–6 months (annual if stable)
Genotypic resistance test	At virological failure
HLA-B*5701	If considering abacavir

BASELINE ASSESSMENT



HIV Monitoring Tool: ongoing patient review

CD4 Recovery

The CD4 T-cell count usually recovers slowly following ART and HIV viral load suppression. Immune function is monitored with 3–6 monthly CD4 counts, with results interpreted as follows:^{2,3}

- for opportunistic infections
- CD4 >500 cells/mm³: normal.

CD4 can be monitored every 6–12 months after 2 years of ART if stable (i.e. viral load consistently suppressed and CD4 count 300–500 cells/mm³).^{2,3}

Morbidity and mortality from several AIDS and non-AIDS conditions are increased in individuals with HIV despite ART-mediated viral suppression, and are predicted by persistently low CD4 cell counts and/or persistent immune activation.³

Because there are no proven interventions to improve CD4 cell recovery and/or inflammation, efforts should focus on addressing modifiable risk factors for chronic disease (e.g., encouraging smoking cessation, a healthy diet and exercise, treating hypertension and hyperlipidaemia).³



• CD4 <200 cells/mm³: severe immunosuppression, may need prophylaxis

• CD4 count 200–500 cells/mm³: moderate immune suppression



HIV Monitoring Tool: ongoing patient review

Virologic failure^{2,3}

Assessing and managing PLWHIV who are experiencing failure of ART is complex, and expert advice should be sought.

Evaluation of virologic failure includes an assessment of adherence, drug-drug and drug-food interactions, drug tolerability, HIV RNA level and CD4 T lymphocyte (CD4) cell count trends over time, ART history, and prior and current drug-resistance test results.

Drug-resistance testing should be performed while the patient is taking the failing ARV regimen, or ideally within 4 weeks of treatment discontinuation. The goal of treatment for ART-experienced patients with drug resistance who are experiencing virologic failure is to re-establish virologic suppression (i.e., HIV RNA levels below the lower limits of detection of currently used assays).

A new regimen should include at least two, and preferably three, fully active agents that are expected to have uncompromised activity on the basis of the patient's ART history and his or her current and past drug-resistance test results.²

- in the regimen.

It is crucial to provide continuous *adherence support* to all patients before and after regimen changes due to virologic failure.^{2,3}

• In general, adding a single antiretroviral agent to a virologically failing regimen is not recommended, because this may risk the development of resistance to all drugs

• For some highly ART-experienced patients with extensive drug resistance, maximal virologic suppression may not be possible. In this case, ART should be continued with regimens designed to minimise toxicity, preserve CD4 cell counts, and delay clinical progression.



HIV Monitoring Tool: ongoing patient review

Co-infections

Patients should be assessed for the risk of co-infections as per the ASHM HIV Monitoring Tool recommendations below:

Assess

Sexually transm

Hepatitis A

Vaccina

Co-morbidities

With the effectiveness of modern ART the ongoing management of PLWHIV has evolved to managing HIV as a lifelong condition in an ageing population. Currently, almost 50% of PLWHIV in Australia are over the age of 50.⁸

Many co-morbidities associated with ageing occur at an earlier age and at greater frequency in PLWHIV², and proactive management is required for the early identification of risk, prevention, and management of these co-morbidities. Over the last two decades cancer, cardiovascular disease and liver disease have become the top causes of non-AIDS related death in PLWHIV.⁹

sment	Frequency
itted infections	Every 3–12 months depending on risk ^{1,4,7}
A, B and C	Annual review ^{1,4}
ations	Annual review ^{1,5}



HIV Monitoring Tool: ongoing patient review

Screening for co-morbidities should be conducted as per the ASHM Monitoring Tool recommendations shown in the tables below:¹

Monitoring for co-morbidities

Assess

Haematolo

Weight

CV Risk (www.cv

Blood pr

Fasting lipids (TC

Fasting

Liver funct

Renal (i) (ii)Urinalysis/protei

Bone (i) Calcium, (ii) FRAX (iii) 25(OH)

Cogn

Depres

BASELINE ASSESSMENT



sment	Frequency
ogy (FBC)	Every 3–12 months
& BMI	Annual review
vdcheck.org.au)	Every 2 years
ressure	Annual review
C, LDL, HDL, TG)	Annual review
glucose	Annual review
tion tests	3–12 months & start or change of ART
) eGFR in/creatinine ratio	3–12 months & start or change of ART Annual review
phosphate, ALP) X score vitamin D	6–12 months 2 years (Consider DXA) As indicated
nitive	As indicated (screen if at risk)
ession	As indicated (screen if at risk)



HIV Monitoring Tool: ongoing patient review

Cancer screening

PLWHIV are at risk of various types of cancers and should be regularly screened as per Australian guideline recommendations.^{1,10–12}

Cancer

Cervical cancer

Colon cancer

Breast cancer

Prostate cancer

Skin cancer

Anal cancer

Ongoing	Method
3 years	HPV testing
2 years	>50 years faecal occult blood test (FOBT) or colonoscopy
2 years	>50 years mammogram
2 years	>50 years consider PSA
Opportunistic	>40 years examination if high risk
Annual	>50 years digital ano-rectal examination (DARE)

ONGOING REVIEW



HIV Monitoring Tool: ongoing patient review

Optimising ART for patients living with HIV

Advances in ART and a better understanding of HIV drug resistance make it possible to consider switching PLWHIV from an effective regimen to an alternative regimen in some situations such as:^{2,3}

- Adverse events
- Development of comorbidities
- Cost

The fundamental principle of regimen optimisation is to maintain viral suppression without jeopardising future treatment options.^{2,3}

It is critical to review a patient's full ARV history, including virologic responses, past ARVassociated toxicities and intolerances, and cumulative resistance test results, before selecting a new antiretroviral therapy regimen.^{2,3}

- Drug-drug or drug-food interactions
- Pregnancy
- Pill burden or the desire to simplify a regimen

• Monotherapy with either a boosted protease inhibitor or an integrase strand transfer inhibitor has been associated with unacceptable rates of virologic failure and the development of resistance; therefore, monotherapy as a switch strategy is not recommended.^{2,3}

• When switching ART in a patient with HBV/HIV coinfection, ARV drugs that are active against HBV should be continued as part of the new regimen. Discontinuation of these drugs may lead to the reactivation of HBV, which may result in serious hepatocellular damage.^{2,3}

 Consultation with an HIV specialist is recommended when planning a regimen switch for a patient with a history of resistance to one or more drug classes.^{2,3}

 Close monitoring to assess tolerability, viral suppression, adherence, and safety is recommended during the first 3 months after a regimen switch.^{2,3}

IE ENT	ONGOING REVIEW	REFERENCES	



Additional resources

- hiv-in-australia/

• Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM). HIV Monitoring Tool. Available at: <u>https://ashm.org.au/resources/HIV-Resources</u>

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You have now completed the pre-requisite learning activity component of the THRIVE Program and are ready to commence the THRIVE Audit.

The audit component requires the review of five PLWHIV to assess if their medical monitoring has been performed in alignment with the recommendations of the ASHM HIV Monitoring Tool.

experienced PLWHIV.

The THRIVE Program was developed by Bastion Med Ed and funded by Gilead Sciences, Australia.



BASELINE ASSESSMENT



Patients included in the audit may be either newly diagnosed or treatment

Clinical expertise was provided by Dr Mark O'Reilly

FRACGP, FAChSHM, MPH, BMED Director, Prahran Market Clinic, Medical Advisor, Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM).

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Abbreviations

ABC, abacavir; ART, antiretroviral therapy; ARV, antiretroviral; CV, cardiovascular; DASS, depression anxiety stress scale; DXA, dual energy X-Ray absorptiometry; eGFR, estimated glomerular filtration rate; FRAX, fracture risk tool; HBV, hepatitis B virus; HBC, hepatitis C virus; HIV, human immunodeficiency virus; K10, Kessler psychological distress scale 10; PLWHIV, people living with HIV.

Bastion Med Ed. 115 Green St, Cremorne VIC 3121. Date of Preparation: December 2020. GIL4464.

BASELINE ASSESSMENT

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ONGOING REVIEW