Package of Care for People Living with HIV

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Mailman School of Public Health

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Background

The ICAP Model of Care is characterized by the delivery of comprehensive and integrated services along the HIV care continuum for adults, children, and pregnant women, with a focus on the family. Other elements of the model include a multidisciplinary team of providers; an emphasis on adherence and prevention; strong linkages between clinical services; and strong linkages with community resources. The ICAP Model of Care defines a Comprehensive Package of Care for adults and children living with HIV that should be considered in all ICAP-supported sites, and within the comprehensive package, a set of Core Interventions that should be prioritized and made available in all sites. The ICAP Package of Care encompasses the full continuum of HIV care from linkage of those found to be HIV positive to retention in care, prompt determination of eligibility for antiretroviral therapy (ART), and initiation of ART with provision of adherence support. "Care", when used here, is defined as all clinical services, including ART, provided to people living with HIV (PLHIV). The evidence-based interventions included in the ICAP Package of Care have been selected based upon their impact on morbidity and mortality, with Core Interventions having the highest impact. Priority should be placed on implementing and achieving targets for the Core Interventions. Programs can also integrate additional interventions into HIV care delivery based upon their epidemiologic, health system, political, and financial context.

The purpose of this document is to describe the Core Interventions included in the ICAP Package of Care, as well as to summarize the evidence supporting them. This document can be used to guide newer programs in establishing HIV services, as well as to remind more established programs about the importance of ensuring high quality implementation of Core Interventions. The target audience includes clinical officers and other technical staff in ICAP country programs. Examples of standard operating procedures (SOPs) and tools developed and used by ICAP country programs to implement the Core Interventions included in the Package of Care are listed in the Appendix.

Comprehensive Package of Care

The Comprehensive Package of Care consists of a package of Core Interventions, as well as additional interventions that can be included according to context and resources.

Core Interventions

The minimum package of interventions that should be provided at all sites includes:

- HIV testing and counseling (HTC), including provider-initiated testing and counseling (PITC) and testing for partners and family members
- Linkage to HIV care of those testing positive from all entry points
- Cotrimoxazole prophylaxis for all eligible PLHIV
- Tuberculosis (TB) screening for PLHIV
    - For those with a positive screen, further diagnostic work-up and treatment
    - For those with a negative screen and/or diagnostic work-up, provision of isoniazid preventive therapy (IPT)
- Assessment of ART eligibility, with prompt ART initiation for all eligible PLHIV
    - WHO staging at every visit, including assessment and treatment of opportunistic illnesses
    - Monitoring of childhood growth and development
    - CD4 testing at enrollment in care and every six months thereafter
- Prevention of mother-to-child transmission of HIV

    - Family planning services to prevent unintended pregnancies in women with HIV infection
    - Provision of ART for all pregnant and breastfeeding women with HIV infection, with a preference for option B+, and ongoing care for HIV-infected mothers and exposed infants
- Medication monitoring and management
    - Monitoring of medication adherence with provision of adherence support
    - Monitoring for, and management of, medication-related side effects and toxicity
    - Monitoring for treatment response and treatment failure, with regimen adjustment as needed
- Monitoring and supporting retention in HIV care
- Access to laboratory testing for HIV diagnosis, determining ART eligibility, monitoring treatment response, and diagnosing TB
    - HIV diagnosis including rapid HIV testing and dried blood spot (DBS)-based HIV-1 DNA PCR for early infant diagnosis (EID)
    - CD4 testing for assessing ART eligibility and monitoring treatment response
    - Routine or targeted viral load monitoring to detect treatment failure
    - Microscopic or molecular TB diagnosis
- Psychosocial support

Additional Interventions

Depending on the epidemiologic, health system, political, and financial context, programs may choose to provide other interventions such as: hemoglobin, ALT and creatinine tests for monitoring medication-related toxicities; assessment and treatment of sexually transmitted infections (STI); hepatitis B surface antigen screening; Cryptococcal antigen screening; cervical cancer screening; malaria services; harm reduction services including opioid substitution therapy/medication assisted therapy; pain management; safe water and hygiene support; nutrition services; mental health services; end of life care; provision of childhood immunizations; and "adolescent-friendly" services and programming. These interventions will not be discussed in this document.

Core Interventions

HIV testing and counseling, including PITC and testing for partners and family members

HIV testing and counseling should be provided through PITC (opt-out testing) in addition to voluntary counseling and testing (VCT). At a minimum, PITC should be provided in TB, family planning, immunization, malnutrition and casualty services, antenatal care and inpatient settings, as well as where services are provided for key populations (including men who have sex with men, commercial sex workers, and people who inject drugs).

PLHIV should be asked about the HIV status of their partners and family members during HIV clinic visits; this information should be documented in the medical record and HIV testing should be encouraged and facilitated for family and household members including children with an unknown HIV status.

Programs may conduct other periodic HTC activities such as "family days" or community-based testing.

Data show that a greater proportion of inpatients undergo HTC when they are tested during hospitalization as opposed to deferring until after discharge.[1] PITC has also been shown to increase HIV case finding in a variety of settings including outpatient, STI, TB, and emergency services.[2] Male partner testing has been shown to improve retention in PMTCT programs,[3-5] uptake of PMTCT interventions,[4,6] and decreased risk of vertical transmission of HIV.[7] Couples testing and counseling, when individuals in a sexual relationship receive HTC services together, can reduce self-reported risk behavior[8,9] without increasing risk of overall

adverse events as compared to individual testing and counseling.[10] Data indicate that HTC of children of PLHIV enrolled in care and treatment programs is very low, and rates of HIV infection among these children can be quite high.[11]

Linkage to HIV care

Facilities offering HIV testing should have a SOP describing the process by which individuals testing HIV positive are linked to HIV care.

Linkage to care should be operationalized with a clear definition and should be documented for each individual testing HIV positive.

Strategies to increase linkage to HIV care include: formal referral systems using escorts or referral forms; on-site point of care (POC) CD4 testing immediately after testing HIV positive; patient education; and SMS reminders. Studies show that individuals who receive POC CD4 testing at the time of testing HIV positive are more likely to link to care than those with standard CD4 testing.[12,13]

Cotrimoxazole prophylaxis for all eligible PLHIV

Cotrimoxazole should be provided to all eligible individuals as per national guidelines, including HIV-exposed and -infected infants and children, adolescents, pregnant women and other adults living with HIV.

Cotrimoxazole, a fixed dose combination of trimethoprim and sulfamethoxazole, has activity against a range of bacteria as well as fungi and protozoa. Cotrimoxazole prevents *Pneumocystis jiroveci* pneumonia and toxoplasmosis in PLHIV, and has also been shown to prevent malaria and some bacterial infections in certain settings. The standard dose of cotrimoxazole in adults is one double-strength tablet (or two single-strength tablets) once daily; age-based dosing is used for infants and children (see dosing charts on the Clinical & Training Unit WIKI). Cotrimoxazole prophylaxis has been shown to have both mortality[14-16] and morbidity[17-19] benefits in PLHIV.

TB screening

Adults living with HIV should be screened for TB at regular intervals as per national guidelines, using a symptom-based questionnaire consisting of current cough, fever, weight loss, and night sweats.

Children >12 months of age living with HIV should be screened for TB at regular intervals as per national guidelines, using a questionnaire consisting of poor weight gain, fever, current cough and contact history with a TB case.[20]

For those with a positive screen, further diagnostic work-up and treatment

Individuals with a positive screen should be evaluated for TB as per national guidelines, given that PLHIV with TB have a high mortality risk.[21,22] Xpert MTB/RIF should be the initial diagnostic test where available; it has greater sensitivity than smear microscopy, and also detects rifampicin resistance.[23]

PLHIV who are diagnosed with TB should be started on TB treatment promptly, and then initiated on ART within two-four weeks of TB treatment initiation, regardless of CD4 count.[24]

TB is the most common opportunistic illness and leading cause of death among PLHIV. Early TB case detection improves patient outcomes[25] and decreases the risk of TB transmission in health care settings, households and communities.[25-27] Clinical trial data demonstrate that initiating ART early during TB treatment greatly increases AIDS-free survival.[28-31]

Strategies to improve early ART initiation among PLHIV with TB include: provision of ART at TB clinics, and provision of TB treatment in HIV clinics.

For those with a negative screen and/or diagnostic work-up, isoniazid preventive therapy

Isoniazid should be given for at least six months to all PLHIV (including children >1 year, pregnant women, and other adults based on national guidelines) with a negative screen and/or diagnostic work-up for TB, regardless of CD4 count, previous TB treatment, or ART status.

There is a substantial amount of evidence showing that isoniazid preventive therapy (IPT) decreases TB incidence.[32-40] Some,[35,41-43] but not all,[32-34,36,44-47] studies have also demonstrated a mortality benefit from IPT.

Assessment of ART eligibility, with prompt ART initiation for all eligible patients

PLHIV should be assessed for ART eligibility and initiated on ART promptly when found to be eligible as per national guidelines.

ART eligibility criteria vary by country and may include pregnancy, comorbid conditions (e.g., TB), serodiscordant couples, and age groups (e.g., children under 5 years of age), as well as WHO stage and CD4 cut-points.

Delays in ART initiation lead to greater mortality, faster disease progression, ongoing HIV transmission, and often incomplete immune restoration.[48-52]

Programs may use strategies such as job aids to assist health care workers with clinical staging and determining ART eligibility or chart review to ensure that eligible patients are initiated on ART promptly.

WHO staging at every visit, including assessment and treatment for opportunistic illnesses

An interim history and physical exam, including assessment of weight, height, and WHO stage, should be performed for all patients at each clinical visit. WHO stage should be recorded and used to determine ART eligibility.

For all children, documentation of growth and developmental assessment should be included in the patient file, and for those <2 years of age, head circumference should be measured and recorded.

Findings suggestive of OIs should prompt further diagnosis and management as per national guidelines.

CD4 testing at enrollment in care and every six months thereafter

CD4 testing should be performed within one month of enrollment into care, ideally at the time of HIV diagnosis. CD4 testing should then be repeated at six month intervals. Results should be reviewed, documented in care files, and used for management according to national guidelines.

CD4 cell count is highly predictive of disease progression and survival, and thus is routinely used as a prognostic indicator[48,53] and to assess ART eligibility in PLHIV.

Prevention of mother-to-child transmission of HIV

There are several components of preventing HIV transmission from mother-to-child including: primary prevention of HIV in women of childbearing age; prevention of unintended pregnancies in women living with HIV; provision of ART for all pregnant and breastfeeding women with HIV infection; and ongoing care of mothers and infants.

Family planning services to prevent unintended pregnancies in women with HIV

Family planning services should either be integrated into HIV care or available through facilitated linkage to family planning clinics.

Prevention of unplanned pregnancies in women living with HIV is critical for reducing perinatal HIV transmission. A study in Kenya demonstrated that a combination approach including free contraceptive provision on-site at an HIV research clinic, as well as contraceptive promotion and counseling, led to increased uptake of contraceptives and decreased pregnancy incidence.[54]

Provision of ART for all pregnant and breastfeeding women with HIV infection, with a preference for option B+, and ongoing care for HIV-infected mothers and exposed infants

ART should be provided to HIV-infected pregnant and breastfeeding women in all maternal and child health service delivery points (including antenatal care settings, reproductive and child health programs and maternity), to reduce the risk of mother-to-child transmission and maternal morbidity and mortality.

Ideally, all HIV-positive pregnant and breastfeeding women should be started on once-daily triple drug therapy,[55-57] in line with the recommended efavirenz-based first-line regimen for non-pregnant adults and adolescents. Preferably, this regimen should be continued for life (Option B+),[58-61] or at least until cessation of breastfeeding in women who do not meet ART eligibility criteria (Option B).[62,63]

Infants should receive ARV prophylaxis at birth, with provision of ongoing care for mothers and infants during breastfeeding and until the infant's final HIV infection status is determined.

The Option B+ approach harmonizes treatment for pregnant and breastfeeding women with that recommended for other adults and adolescents. It also assures that all women eligible for treatment start ART for their own health, while providing additional benefits including preventing mother-to-child transmission in future pregnancies as well as reducing the risk of sexual transmission in serodiscordant couples.

Monitoring medication adherence, side effects, and treatment response

PLHIV on medications including ART, cotrimoxazole, and IPT should be monitored for adherence, side effects and treatment response, with provision of adherence support and management of toxicity and treatment failure.

Monitoring and supporting adherence

Adherence should be assessed at every clinical visit, and ideally also at the time of pharmacy refills, in all PLHIV on ART and/or other medications, including cotrimoxazole and IPT. If possible, drug pick-ups should also be monitored, to identify individuals at high risk for inadequate adherence. A standardized method to assess and record adherence should be devised and implemented.

One commonly-used method for assessing adherence is to ask patients about the number of missed doses in the prior week and the prior month. It is also helpful to ask about reasons for missed doses, in order to provide advice on strategies to improve adherence. Adherence can be assessed by care providers, pharmacists, peer counselors, or other cadres; the person responsible for assessing adherence should be specified and should use the accepted approach for assessment to ensure that it is routinely performed and documented. Monitoring drug pick-ups is also helpful to identify patients at high risk for inadequate adherence, so that they can be targeted for adherence support.

Poor adherence to ART predicts disease progression,[64] emergence of drug-resistance mutations[65] and treatment failure.[66] Reviews on adherence support have shown that adherence counseling, as well as other interventions including food supplementation in food-insecure individuals,[67] SMS text messages[68,69] and directly observed therapy with community health workers[70] can improve self-reported adherence and virologic suppression.[71-74]

Monitoring for side effects and managing toxicity

All PLHIV on ART or other medications including cotrimoxazole and IPT should be assessed for side effects at every visit, through both history-taking and a targeted physical exam.

Individuals suspected of medication toxicity should be managed as per national algorithms, including referral for consultation and/or laboratory tests as indicated.

Monitoring for treatment response and management of treatment failure

Patients on ART should be regularly evaluated for treatment response using laboratory (viral load or CD4 testing) criteria, or if not available, clinical (WHO staging) criteria.

After six months of ART, patients should be monitored for treatment response with viral load if available or if not, with CD4 and/or clinical criteria. Viral load monitoring has better sensitivity and positive predictive value for detecting treatment failure than clinical or immunologic monitoring,[75-80] and is recommended as the preferred method of monitoring PLHIV on ART in the 2013 WHO guidelines.[24] However, many programs do not have access to viral load testing, in which case immunologic and/or clinical criteria for pediatric and adult populations as per national guidelines should be used to detect, as well as manage, treatment failure.

Monitoring and supporting retention in care

Implementation of an appointment system and a method to track PLHIV enrolled in care, as well as interventions to support retention, should be implemented to minimize loss to follow up.

HIV is a chronic disease necessitating lifelong care, thus appointment systems are essential for ensuring that patients receive regular follow-up and health care workers are able to track and support patient retention. Extra attention may be needed for those at high risk of loss to follow up, including men, younger adults, and those not eligible for ART. Studies have shown that mortality is high among PLHIV not retained in care.[81-83]

A number of strategies can be employed to support retention in care. A study in Kenya showed that providing free cotrimoxazole to PLHIV ineligible for ART increased retention.[84] Utilization of community-based groups of patients for ART refills and adherence assessments has also been shown to increase retention.[85] SMS text messaging has been shown to improve attendance in some outpatient settings,[86,87] and is currently being studied specifically for HIV care.

Access to laboratory testing

Access to quality-assured laboratory tests along the continuum of care is vital, either through onsite capacity building or establishment of specimen transport systems. These include: HIV diagnostic services such as rapid HIV testing and DBS-based DNA PCR testing for EID; monitoring tests including CD4 testing and in some settings, HIV viral load; and access to smear microscopy and/or Xpert MTB/RIF for all PLHIV enrolled in care.

Psychosocial Support

Psychosocial support is essential to all areas of HIV care and should be integrated into the above Core Interventions.

Some programs use peer educators, expert clients, volunteer health workers, or support groups as a means of supporting patients, particularly in areas such as adjusting to an HIV diagnosis, linking to care, adhering to ART, and remaining in care.

Appendix

Following are examples of SOPs and tools to support implementation of core interventions in the ICAP Package of Care.

SOPs and Tools to Support Implementation of Core Interventions in the ICAP Package of Care*
HIV Testing & Counseling
SOP for PITC (generic)
Family Testing Form (Ethiopia)
Family and Partner Testing Cue Card (generic)
Linkage to Care
SOP for Linkage and Retention (Swaziland)
Linkage Job Aid (Kenya)
Cotrimoxazole Prophylaxis
Cotrimoxazole Job Aid (Ethiopia)
TB Screening
TB Screening and IPT Forms - infants, children, and adults (Ethiopia)
Assessment of ART Eligibility
ART Eligibility Checklist (Swaziland)
Preventing Mother-to-Child Transmission
Family Planning Screening Tool (generic)
Family Planning Site Assessment Tool (generic)
Option B+ Flow Charts - ANC, labor & delivery, breastfeeding (Ethiopia)
PMTCT Counseling Flip Chart (generic)
B+ Retention Monitoring Tool (generic)
Monitoring Adherence, Side Effects, Treatment Response
5 Steps for PLHIV Job Aid (Ethiopia)
Retention in Care
SOP for Linkage and Retention (Swaziland)
Laboratory Testing
Dried Blood Spot SOP (Ethiopia)
Dried Blood Spot Result Tracking Tool (Tanzania)

*These are examples and may require adaptation to reflect the most recent national guidelines

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