ART in MSF programmes

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Basic interventions to be in place in all MSF projects

- Universal precautions
- Safe blood transfusion
- Treatment of STI
- Condom availability in health services

HIV/AIDS PROJECTS= ACCESS to ART

- **IEC** to ensure awareness and promotion of services
- **VCT**
- Treatment of **OI and ART**
- **PMTCT**

MSF ART Experience

- MSF started HIV/AIDS programs in the 90's
- Started to provide free ART in 2000
- Update September 2005:
  - 55 projects in 29 countries
  - 56.420 started on ART
  - 43.893 (78%) still on ART
  - 0.5% patients on second line

MSF-E HIV/AIDS projects

Project	Context	Start ART
Busia, Kenya	Rural	July 03
Bulawayo, Zbw	Urban	April 04
Tsholotscho, Zbw	Rural	Sept 05
Kapiri, Zambia	Rural	Sept 04
Dowa, Malawi	Rural	Dec 04
Makete, tanzania	Rural	Jan 05
Puerto Barrios, Guate	Semi-urban	Oct03
Guayaquil, Ecuador	Urban	June 04

MSF-E HIV/AIDS projects

- All are comprehensive projects including preventive and curative care, IEC and advocacy component
- All these projects are integrated in MoH structures and HHRR are shared
- They are vertical projects tackling mainly HIV/AIDS

Description of patients

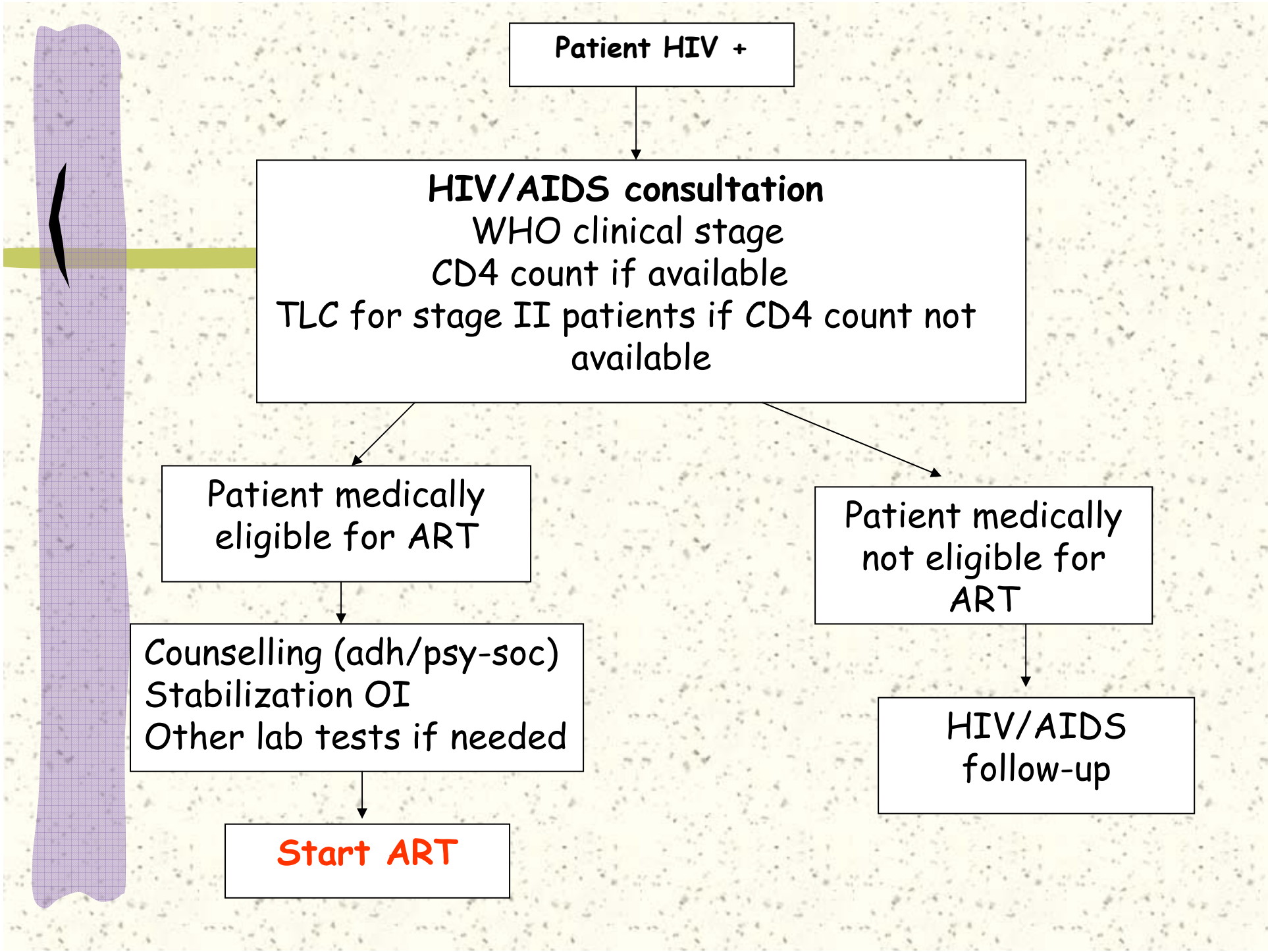
- 65% are women
- 70% are stage 3 and 4
- 20% has CD4 < 50/mm^3
- 60% has CD4 < 200/mm^3

Results

- 10.659 HIV+ patients enrolled
- 4.773 on ART
- Adherence >95% in 98% of patients
- CFR:7.1%
- LFU:2.8%
- Patients on second line:0.9%

Results: children

- 1.1191 children enrolled
- 533 children on ART
- CFR: 9%
- All children > 10 Kg are treated cutting adult FDC


Patient HIV +
HIV/AIDS consultation
WHO clinical stage
CD4 count if available
TLC for stage II patients if CD4 count not available
Patient medically eligible for ART
Counselling (adh/psy-soc)
Stabilization OI
Other lab tests if needed
Start ART
Patient medically not eligible for ART
HIV/AIDS follow-up

Eligibility criteria

- **Medical criteria:**
  - WHO stage +/- CD4
- **Psycho-social criteria:**
  - Good understanding ART implications
  - Disclosure (strongly recommended)
  - Regular attendance to the clinic (adherence CTX prophylaxis)
  - Past history: addiction, active mental illness

Patient flow: 1st ART consultation

Medical staff (MD, CO)

- Evaluate medical criteria
- Diagnose any OI(specially TB)
- Assess adherence to CTX prophylaxis
- Do additional tests if required

Adherence counsellor

- Initial education session
- Discuss benefit of disclosure

Patient flow: 2nd ART consultation

Adherence counsellor

- Evaluate patient's understanding and expectation of ART
- Clarify issues regarding ART and reinforce adherence
- Review lab results if any

Patient referred to clinician only if new medical problem

Patient flow: ART starting visit

Clinician

- Review ART understanding and adherence
- Start ART with detailed description of drug dosing
- Explain ART side effects and what to do if adverse reaction occurs

Patient flow: ART follow up visits

- Close follow up on medical and adherence during the first 3-6 months
- Visits with **MD/MA/CO** at week 2, month 1, 2 and 3 = side effects and IRS
- **Adherence counsellor**, individual or group sessions at week 2, month 1, 2 and 6.
- If patients are stable they can be followed by **nurses** after 3 months

Laboratory monitoring

Tests done	D0	W2	M1	M3	M6	M12
Pregnancy test	X					
ALT	X	X	X			
Hb	X		X	X	X	X
TLC	X				X	X
CD4	X				X	X

First line treatment

D4T or AZT
+
3TC

+ NVP or EFZ

NRTI/NNRTI regimen

First line treatment

- FDC d4T+3TC+NVP is the most widely used 1st line combination in MSF projects
- Patients are switched to AZT or EFV depending onside effects and/or drug interaction (NVP-RMP)

Quality of drugs in various markets

	Highly regulated countries			Developing countries		
Quality Assurance	*Branded products*	*Generic products (for domestic market)*	*Products to be exported to less regulated countries*	*Generic products (for domestic market)*	*Generics to be exported to highly regulated countries*	*Products to be exported to less regulated countries = Multi source generics*
Control of the manufacturer	Yes	Yes (+/-) can be delegated	Theoretical	Variable	Yes	No
Quality of API's	Yes	Yes	No	No	Yes	No
Clinical studies	Yes	NA	NA	NA	NA	NA
Therapeutic equivalence	NA	Yes	No	No	Yes	No
Stability studies	Yes	Yes	Weak	No	Yes	No
Packaging/Labelling/Insert	Yes	Yes	No	No	Yes	No
Independant quality control	Yes	Yes	No	No	Yes	No
Secured distribution channels	Yes	Yes	No	No	Yes	No
Pharmacovigilance	Yes	Yes	No	No	Yes	No
Quality monitoring	Yes	Yes (+/-) can be delegated	Theoretical	No	Yes	No

Quality of drugs in various markets

- What can we conclude?
  - Quality is linked to the destination of a product rather than to its origin
  - High risk in developing countries

Qualification standards

- WHO Good Manufacturing Practices
- WHO pharmaceutical products specifications
- WHO guiding principles for assessing the acceptability of pharmaceutical products
- WHO guidelines regarding the assessment of multi-source products
- Internationally recognized pharmacopoeia (EP, BP, USP, Int. P…)
- MSF labelling and packaging specifications

Qualification standards

- No duplication of existing work
- The following products are considered validated for MSF :
  - WHO pre-qualified products
  - Products registered, and on the market, in ICH countries (EU, US and Japan)
- MSF validation does not supersede in any way NDRA prerogatives

Horizontalization of HIV/AIDS

- **Horizontalization:**
  - Avoid discrimination (positive:vertical projects, negative: ignorance HIV problem)
  - Need of task shift and de-specialization AIDS care)
- **Simplification:**
  - Increase access
  - Use of experience gained from AIDS projects

First level of care
(health post)

- Preventive component: health education, condom distribution, FP, UP
- STI management
- VCT
- Clinical Staging (WHO)
- Follow up stage 1 and 2. Refer 3 and 4
- Provide CTX prophylaxis
- Treatment simple OI (mucocutaneous, diarrhoea, respiratory infections...)
- Recognition SAM and MAM
- Dietary advice

First level of care: resources

- **Staff**: nurses, nurse assistants, lay providers, TBAs
- **Services**: OPD, MCH, ANC, health education

  Probably follow up TB continuation phase

  No laboratory

Second level of care
(health center)

- All the previous +
- Start and follow up ART
- First line (adults and children)
- Manage toxicities/interactions first line
- Identify failure or suspicion of failure

Second level. resources

- **Staff:** MO, CO, nurses, midwifes, NA
- **Services:** OPD, ANC, MCH, IPD, TB clinic, deliveries
- **Laboratory:** malaria, stool, urine, pregnancy test, AFB, HB and TLC
- **Optional:** biochemistry, CD4

Third level: District Hospital

- Management of complicated OI
- Management MAM and SAM in need hospitalization
- Evaluation failure in adults and children
- Second line ART start and follow up

Third level: resources

- Staff: + MD
- Services: IPD capacity, surgery
- Laboratory: basic + biochemistry (liver and renal function), amylases/lipase, microbiology (indian ink,analysis CFR)
- Blood transfusion
- Radiology: Chest Xray

Where do we start?

- We don't start at first level if second level is not in place (provision of ART should be ensured).
- We **should start** at second level (HC) and ensure reference from and to first level
- In existing HIV/AIDS projects where we already work at third level, decentralize at second and/or first level with simplified strategies

Monitoring

- **Do we need CD4?**
  - Desirable, not required
  - Useful to monitor response more than decide starting HAART
- **Do we need liver function?**
  - NVP liver toxicity: Is ALT rutine monitoring useful? Can we do it with clinical algorithms?
- **Do we need haematology?**
  - FBC can guide decision to start in stage 2
  - Hb when using AZT

Conclusions on monitoring 1st line treatment

MINIMUM LAB REQUIREMENTS

- CD4 not needed
- Liver test not needed
- Haemoglobin if on AZT
- Pregnancy test if EFV

CLINICAL MONITORING AND ADHERENCE ARE CRUCIAL!!!!!!!!!!!

Main points to take into account

- Counselling and adherence
- Detection and treatment of OIs
- Referral of complicated OIs
- Development of IRS
- Detection of failure
- Referral for second line

Sustainability: whose role it is?

- MSF role is to provide patients with the best treatment and to have a "starter role" where access to ART is not available.
- Our projects are usually integrated in MoH structures, and have a strong training component
- We believe it is the MoH who has the final responsibility towards its population
- Patients should be empowered to take decisions
- Programs need careful planning including attention to long term stability and equity. Yet these considerations should not paralyze us to start

Guidance on ethics and equitable access to HIV treatment and care (UNAIDS-WHO 2004)

- Uncertainty is inevitable when planning the scale-up of programs but the possibility that ART may become unavailable for some patients in the future is not a good reason for not starting them on it now
- "Look at the patients who have been treated. Would you rather that we let them all die back , when we could have saved them?"