Medecins Sans Frontieres Khayelitsha

SUPPORTING ADHERENCE TO ANTIRETROVIRAL TREATMENT: A FACILITY APPROACH TO REDUCE THE RISK OF TREATMENT FAILURE

REPORT AND TOOLKIT

MEDECINS SANS FRONTIERES

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Western Cape Government

Health

1. BACKGROUND:

The rapid scale up of antiretroviral treatment (ART) coverage in South Africa has improved access to treatment for HIV positive patients significantly. However, expanding treatment programmes are now facing increases in the number of patients failing treatment.1 For optimal clinical outcomes, adherence to ART should be greater than 95% (1-2 missed doses per month); when adherence falls below 80% (more than 6 missed doses per month), detectable viral loads begin to appear.2 Prolonged periods of replicating virus in the presence of suboptimal levels of ART in the bloodstream allow the virus to develop mutations that lead to resistance to the different classes of ART.

1.1 WHAT IS POOR ADHERENCE?

Poor adherence can vary from occasional missed doses to chronic, longer term treatment interruptions. Adherence can also reflect the quality of the relationship between the patient and the health care provider. Routine viral load monitoring is available in South Africa, which should be used to improve the detection of patients with an elevated viral load who are at risk of treatment failure. Thus the clinician also has a role to 'adhere' to routine viral load monitoring and to act on every viral load result.

'I now feel very confident and skilled to manage patients with high viral loads.'

1.2 WHY ADHERENCE SUPPORT?

The South African national ART guidelines require patients with an elevated viral load greater than 1000 copies/mL to undergo an 'intense adherence assessment.'3 The structure and content of this counselling varies across sites, due to a lack of clear guidelines to direct the clinician, or counsellor. Often the counselling focuses on repeated treatment literacy concentrating on the importance of good adherence, rather than a structured problem solving approach for common causes for poor adherence (lack of disclosure, misconceptions of ART, alcohol abuse, migration, among others). Group sessions or adherence support groups for high risk groups are very rarely utilized, despite being more feasible, given limited resources. Lastly, clinicians often struggle with the decision to switch patients to a second line regimen, with the knowledge that adherence difficulties need to be attended to prior to initiating a more complex and costly regimen.

2. THE RISK OF TREATMENT FAILURE (ROTF) PROGRAMME:

In February 2012, Medecins Sans Frontieres (MSF) partnered with Western Cape Government Health to pilot a 'risk of treatment failure' intervention at a large community health centre ART clinic. Ubuntu Clinic provides ART to close to 7 000 adult patients, of whom approximately 10% are currently receiving second-line treatment.

2.1 IN A NUTSHELL

The purpose of the Risk of Treatment Failure (ROTF) programme is to provide structured adherence support for patients with high viral loads; prolong the duration of viral load suppression on first- or second-line ART; ensure timely and successful regimen changes; decrease the development of treatment resistance and limit the need for 3rd line ART. The ROTF programme consists of four components:

- a flagging system to identify patients with viral loads greater than 400 copies/mL,
- counsellor led adherence support groups,
- combined clinical and adherence support consultations by a nurse authorized to initiate and manage ART (NIMART), using structured steps to improve adherence to ART, and
- access to ART Adherence Clubs[4,5] for patients that complete the ROTF programme and return to an undetectable viral load.

The programme has been implemented as part of routine clinic services using a provincial staff team of nurses, counsellors, and reception staff; all members of the team have been trained and mentored on the programme, and competency assessments are completed at the end of mentorship. The following is a brief description of the model:

'I no longer feel frustrated not knowing what to say and do with patients with high viral loads, I can see them with a smile.'

FLAGGING PATIENTS WITH DETECTABLE VIRAL LOADS

As patients arrive at the reception area, a simple system has been implemented to ensure that patients whose most recent viral load measurement is greater than 400 copies/mL have their folders flagged and separated. The flagging system involves reception staff checking the most recent viral load result (either manually or through the clinic's electronic medical record system) and placing a red sticker on patient folders with elevated viral loads. If a patient returns to having an undetectable viral load after the programme, a green sticker is placed to cover the red one.

ADHERENCE SUPPORT GROUPS

All patients with one or more elevated viral loads (those folders flagged with red stickers) are requested to attend the 'high viral load' adherence support group session which takes place daily at the facility prior to their clinical consultation. A trained counsellor facilitates the discussion around understanding ART adherence and the flexibilities allowed, rectifying myths and misconceptions, and sharing barriers to adherence. The counsellor also reviews basic education about viral load and the correlation between poor adherence and a detectable viral load. Grouping patients, who are all experiencing a high viral load, promotes openness and honesty. It furthermore gives patients a chance to motivate and support each other. Counsellors, who undergo a basic mentoring program, follow a structured predetermined session plan to facilitate such support groups.

INTEGRATED CLINICAL/ADHERENCE SUPPORT CONSULTATION

Following the support group, each patient with a consecutive high viral load receives an individual consultation with a nurse (red boxes). The consultation includes two components: 1) structured adherence support and 2) clinical management of the patient. Clinical management includes viral load monitoring and, if necessary, preparing patients to switch to second line ART, both according to the country's national guidelines.3 The adherence support component is made up of four sessions that occur monthly which includes a repeat of the viral load and the result communicated to the patient.

STRUCTURED ADHERENCE SUPPORT SESSIONS:

The four sessions consist of practical standardized steps to simplify adherence and problem solve with the patient around common adherence barriers, all in a non-judgemental way. The nurse is required to discuss:

- a medication schedule to fit into the routine of the patient's daily life, allowing flexibility where appropriate;
- where and how to keep extra/emergency doses on hand;
- a simple reminder strategy;
- a plan for taking ART when using substances or suffering from depression;
- a back up plan for getting to clinic appointments and a plan for holidays and out of town trips.

The nurse also normalises making mistakes with adherence and motivates the patient to try again. The nurse and the patient determine an adherence plan together during the 5-10 minute consultation. A simple one page adherence session plan is placed in the patient's folder to keep a record of the patient's four adherence sessions.

STRUCTURED ADHERENCE SUPPORT SESSIONS:

It is important to follow your DOH national ART guidelines when deciding on viral load monitoring and regimen switches. Decisions on the clinical management of virologic failure will depend on the patient's current regimen. Currently in South Africa:

PATIENTS ON FIRST LINE ART:

Where the second consecutive viral load is more than 1000 copies/ml, the patient will undergo a regimen change from 1st line to 2nd line ART. Patients will remain in the 'risk of treatment failure intervention' for a further 3 months until viral load is repeated on the new 2nd line regimen.

Where the repeat viral load is undetectable the patient will exit the ROTF programme. If the nurse considers club/CAG membership an appropriate mechanism for such patient's continued follow up care and treatment, the patient will be referred to join an ART adherence club (green). If a club is not suitable, the patient is referred back into routine clinical care.

Patients whose viral load is between 400 and 1000 copies/ml will remain in the ROTF programme for a further 3 months until VL is repeated again. Patients with a viral load between 400 and 1000 copies for greater than one year's duration will be considered for switching to second-line ART.

PATIENTS ON SECOND-LINE PROTEASE INHIBITOR ART:

Patients with detectable viral load measurements on second-line will also automatically qualify for the full ROTF programme as above. If available, genotype testing should be performed for patients on second- line ART with consecutive viral loads > 1000 (in accordance with national guidelines) when adherence barriers have been dealt with or excluded. Where a genotype test shows resistance to lopinavir/ritonavir, a third-line regimen will be determined according to genotype results. Third-line drugs, not currently available in the public sector, can be provided by MSF for the duration of the patients treatment or until they are available in the public sector.

Where a genotype test shows no resistance to lopinavir/ritonavir, patients will continue on second-line ART and remain in the ROTF programme, with medical officer supervision, for a further 3 months. A viral load test will be repeated and if still detectable, patients will exit the intervention as unsuccessful.

Once a follow up viral load is undetectable (VL < 400copies/ml) on second- or third-line ART, the patient will exit the ROTF programme. The patient can be referred to join an ART adherence club (green) or referred back into routine clinical care.

These combined consultations (adherence sessions and clinical management) are run by nurses and supported by doctors. Nurses undergo a short training and mentoring programme to be able to manage these patients comprehensively. Mentorship on the ROTF programme increases NIMART authorized nurses' confidence to manage and support patients at risk of treatment failure.

3. PATIENT FLOW:

PATIENTS WITH FIRST ELEVATED VL

Routine consultation with clinic nurse.

PATIENTS WITH CONSECUTIVE ELEVATED VL

Individual consultation with ROTF nurse

Combined adherence support and clinical management.

See worksheet and reference document on CD

CLINIC PHARMACY

ADHERENCE SUPPORT GROUP:

Facilitated by a counselor

See Support Group guidelines on CD

PATIENTS WHO GO ON TO SUPRESS THEIR VL

ADHERENCE CLUB/ CAG

START

RECEPTION STAFF:

Flags Folders with an elevated viral load (VL)

Checks all folders as patients present to retrieve their folders for their appointment

DATA CAPTURERS:

Flags Folders with an elevated viral load (VL)

Flag folders as blood results are captured and filed

4. OUTCOMES:

‘You build a relationship with your patient, which helps your patient to trust you and talk freely. Only then can you get to the bottom of the adherence issue.’

TOTAL UBUNTU PATIENTS ON ART

7153 Ubuntu patients on ART

88% are first-line ART patients

11.5% are second- line ART patients

0.06% are third- line ART patients

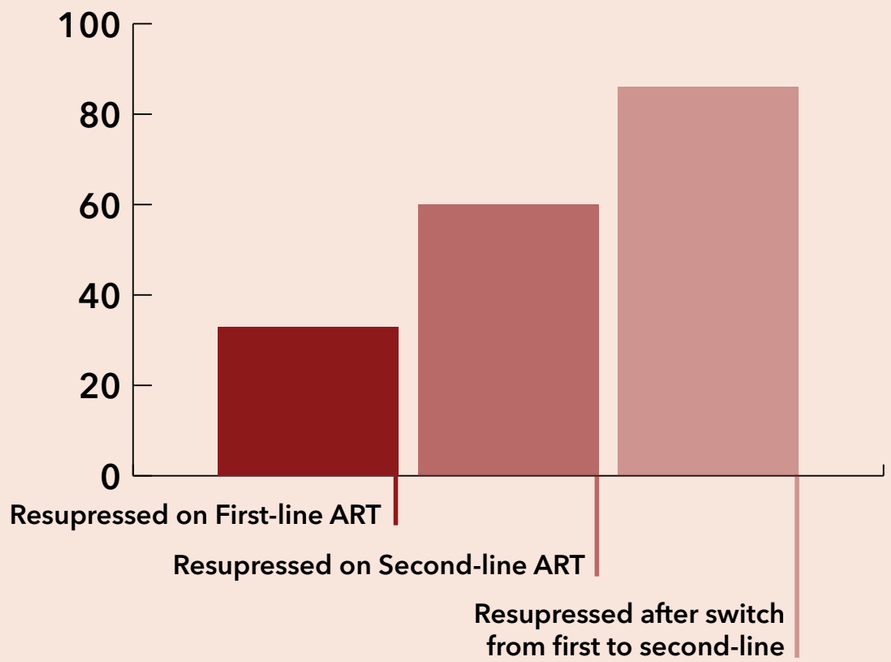
ANALYSIS OF PATIENTS ENTERING THE ROTF PROGRAMME -

722 patients entered the ROTF programme

69% entered on first-line ART

31% entered on second-line ART

RESULTS OF THE ROTF PROGRAMME -



5. LESSONS LEARNT

Routine viral load monitoring, identifying patients with high viral loads, and addressing adherence promptly, are essential components of the ART programme in South Africa.

Supporting and managing patients with detectable viral loads requires a team approach involving all clinic staff at a facility – doctors, nurses, counsellors, reception staff, and pharmacists.

The adherence counselling component of such support cannot be the work of lay counsellors alone;

Training and mentorship on the ROTF programme equips NIMART authorized nurses to confidently and competently manage patients with high viral loads.

Combining adherence and clinical management during nurse consultations increases the number of appropriate switches from first- to second-line ART ensuring adherence support.

The ROTF programme is a feasible intervention to implement in all existing ART clinics.

Third line ART should not be the main focus of this programme. Only a small minority of patients will eventually require third line ART. The majority of patients need adherence support interventions.

Providing access to ART Clubs for patients who have previously struggled with adherence (often due to the cost and time associated with returning to facilities regularly), supports continued adherence by ensuring quick easy access to ART supply and peer support going forward.

This programme supports patients through a difficult period in their treatment journey and empowers patients to take control of their own treatment. Introducing flexibility into patients' understanding of adherence ensures long term adherence.

National guidelines for structured adherence support are urgently needed.

6. REFERENCES

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Wilkinson L, Adherence clubs: A long-term retention strategy for clinically stable patients on antiretroviral therapy, SAHJM June 2013

7. APPENDICES

1. Overview

2. Tools
   - Counsellor's tools
   - Nurse's tools