HIV DRUG RESISTANCE AND STEWARDSHIP
3RD LINE PROGRAMME

SOUTHERN AFRICAN HIV CLINICIANS SOCIETY CONFERENCE - 2014

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20 YEARS OF FREEDOM
South Africa 1994 - 2014

ANTIMICROBIAL STEWARDSHIP

The responsible use of a ***critical*** and ***threatened*** health resource we depend on to prevent and treat infectious disease.

Why is it needed?

Rising resistance rates

Limited manufacturing pipeline of new agents

Morbidity burden and large costs associated with improperly treated disease

Conserve what we have

ANTIMICROBIAL STEWARDSHIP

Implies:

- appropriate clinical decision-making for individual patients

- a population perspective that maximises overall benefits, minimises adverse events and costs

Delays the onset of widespread resistance to commonly used agents.

ANTIMICROBIAL STEWARDSHIP INTERVENTIONS

- Specialist intervention
- Formulary restriction
- **Pre-authorisation**
- Guidelines (indication, dose, duration)

THIRD LINE PROGRAMME

Third line ARV peer review committee (PRC)

Protocol

Motivation form

Recommendation

Standard operating procedures

First public sector third line ART access programme in the world.

THIRD LINE ARV PEER REVIEW COMMITTEE (PRC)

Clinicians with expertise in resistance

- Adult group
- Paediatric group

Terms of reference includes:

- The development of a standard protocol for third line ART for adults and paediatrics.
- Make recommendations pertaining to placing of individual patients on third line regimens based on specific criteria in the standard protocol, i.e. resistance testing, adherence, etc.

Screening

- Administrative, assign a number
- Sent to Committee for consideration

Decision making

- Consensus after the evidence is considered and other relevant issues are taken into account.

PROTOCOL

Adherence

Treatment failure while on a second line PI regimen often due to non-adherence.

80% or more of doses correctly taken for at least 3 months has been measured **objectively.**

Adherence improvement

If the VL is detectable subsequently on a PI regimen, and all adherence interventions have failed, refer patient to a designated specialist site ***while still taking the regimen***.

PROTOCOL

Genotype resistance test

- Expensive
- Recommended if good adherence has been verified objectively **and** the patient has been on PIs for at least a year.
- Children on NNRTIs - resistance testing done after confirmed failure.

Maintain patient on current antiretroviral therapy - resistance testing **must** be performed whilst the patient is taking the antiretroviral therapy regimen they are failing

PROTOCOL

Indications for resistance testing

- All newly diagnosed infants whose mothers failed ART during pregnancy or breastfeeding.

- All patients with documented virologic failure on a PI regimen who have previously been treated with an unboosted PI.

- All patients failing a LPV/r regimen who received TB treatment while on LPV/r without appropriate dose adjustment
- (double dose LPV/r for adults and “super-boosted” LPV/r plus ritonavir in children).

- All adult patients failing 2nd line regimens for more than 12 months

MOTIVATION FORM

REQUEST FOR THIRD LINE ANTIRETROVIRAL THERAPY																			
PATIENT DETAILS																			
Patient First Name																			
Patient Surname																			
Date of Birth day/month/year									**Patient number**										
Identity number														**Age**		**Gender**	M/F		
Weight			**BMI** (kg/m²)				***Height (child)***												
FACILITY DETAILS																			
Facility Name																			
Doctor In Charge Of Patient/ Authorised Prescriber																			
Doctor's Contact Number																			
Doctor's Email Address																			
Signature of Authorised Prescriber														Date					
Past medication history:																			
Date started / **Date stopped**									**Regimen**							**Reason for discontinuation**		**Concurrent TB therapy**	

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REGIMEN

No empiric third line regimen

Determined by genotypic resistance tests

If PI resistance mutations present

- darunavir-ritonavir

and depending on resistance profile

- raltegravir and etravirine

STANDARD OPERATING PROCEDURE

Recommendation sent to:

- Doctor in charge of patient
- Heads of Pharmaceutical Services
- Provincial HAST Manager / Medicine monitor
- Depot Manager

STANDARD OPERATING PROCEDURES

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DOCUMENT CONTROL:
Copy Number: .....
Issued to: .....
Received by: .....
Period Effective:
.....
Adapted & copy to
CPU:.....
Date:.....

STANDARD OPERATING PROCEDURE

SOP Number		**Revision NO:**	
SOP Title	**3rd Line Therapy Orders**		
Institution	National Department of Health		
Issue Date	February 2014		
Effective date	February 2014		
Number of pages including cover			
Original author of the SOP	Central Procurement Unit		
Issued by	NDoH: Affordable Medicines Directorate		

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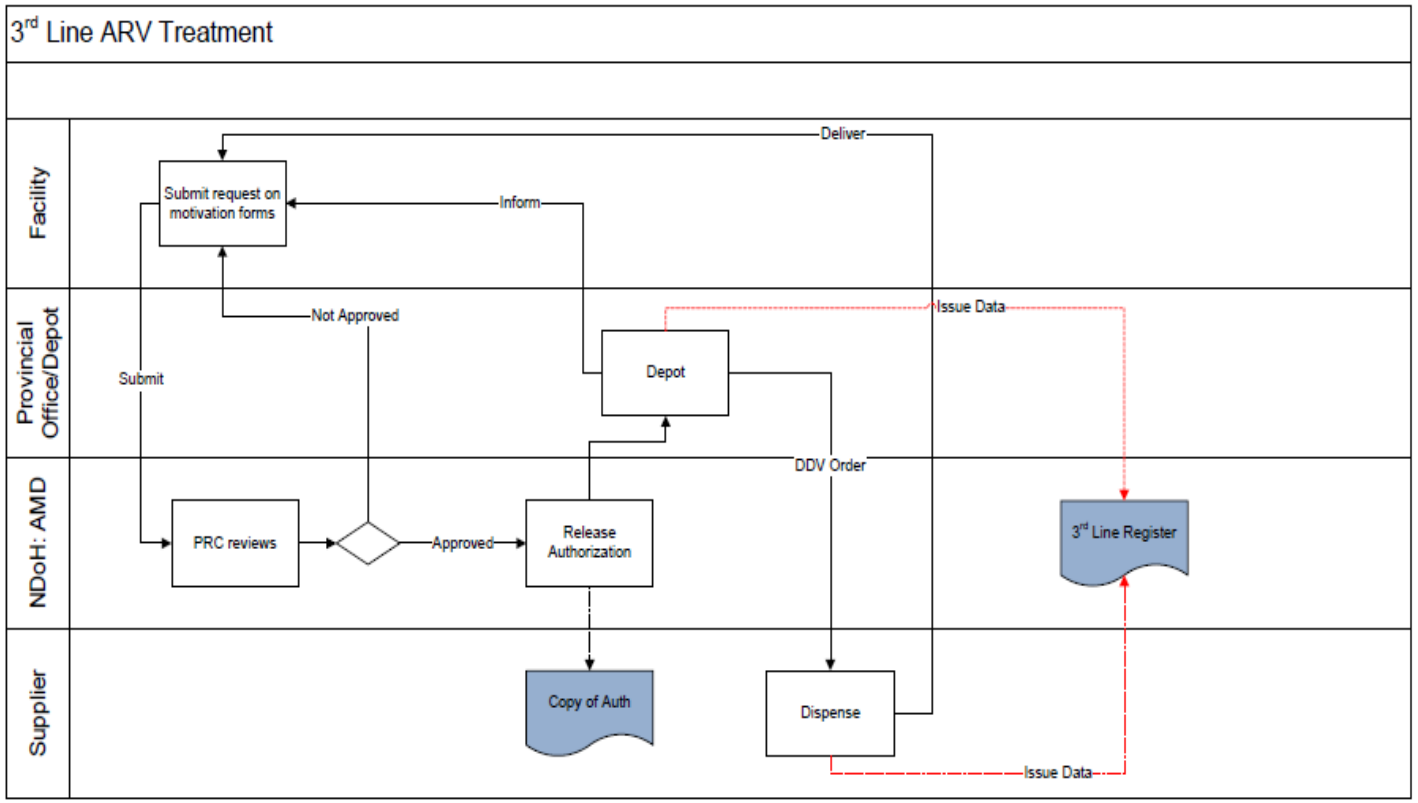
Process Flow:



CHALLENGES

- Incomplete forms
- Scanned forms too large
- Resistance test – Stanford
- Resistance test done while patient was not on treatment
- Timelines
- Protocol not adhered to
- Supply issues

SUCCESSES

- Patients appropriately placed on treatment
  - Children
  - Adults
- Research (patient characteristics, resistance patterns, regimens used and response to therapy)
- Educational opportunities, dialogue
- Guideline development

Acknowledgements

- Prof Mendelson
- Third Line ARV Peer Review Committee

Questions?