

SATuRN: Preliminary report 2011
Southern Africa Treatment and Resistance Network

PRELIMINARY REPORT 2011

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Foreword

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HIV Drug Resistance Satellite Meeting of the 5th South African AIDS Conference



The HIV Drug Resistance Satellite session:
We would like to bring to your attention the HIV Drug Resistance Satellite Meeting of the 5th South African AIDS Conference, on the 7 of June 2010 (9am – 1pm), at the International Conference Centre (ICC), Durban, South Africa. The meeting includes theoretical lectures and clinical cases on the usage and interpretation of HIV-1 drug resistance genotyping in the management of HIV patients on anti-retroviral (ARV) treatment. This meeting is targeted at clinicians, clinical virologists, nurses, medical students and researchers working in the public and private sector who are currently involved in the treatment of patients with ARVs in Southern Africa.

Presenters:

Prof. Jeffrey Klausner, CDC/PEPFAR.
Prof. Wendy S Stevens, Wits and NHLS
Prof. Francesca Conradie, Wits
Dr. Gillian Hunt, NICD
Dr. Tulio de Oliveira, Africa Centre and UCL.

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20 years of primary drug resistance studies in South Africa

Introduction:

The development of HIV-1 drug resistance poses a major threat to sustaining these achievements, particularly in settings where limited resources prevents regular laboratory monitoring of response to ART and complex ARV regimens.

Objective:

To describe the trend in the prevalence of transmitted drug resistance (TDR) in South Africa over the past 20 years and to compare the results obtained from the Africa Centre's 2010 populations based HIV surveillance in rural KwaZulu-Natal.

Results:

Eight published data sets (Pillay et al, 2002; Gordon et al, 2003; Bessong et al, 2005, 2006; Seighe et al 2007; Jacobs et al, 2008; Pillay et al, 2008; Huang et al, 2009) were selected for analysis from a total of **32 HIV drug resistance studies**. Additional sequences published through non-drug resistance articles (Matthews et al, 2008) were also retrieved from Genbank and included in the analysis. The total number of **sequences analyzed was 1650**.

Data source and Methods:

A comprehensive literature search was conducted on PUBMED to identify papers on drug resistance in treatment naive patients that had been published within the past 20 years in South Africa. The key search terms used were "HIV-1 AND Drug resistance AND South Africa". Seventy two (72) sero-positive samples from recent sero-converters from northern rural KwaZulu-Natal were genotyped. They were selected from participants of Africa Centre's 2010 annual adult population based HIV surveillance.

The **prevalence** in transmitted drug resistance over the past 20 years has remained low. There was no evidence of transmitted resistance prior to the year 2000 (n = 32). The year with the highest level was **2002 (6.67%, 95% confidence interval (CI): 3.09-13.79%; n: 6/90)**. After 2002, the prevalence remained below 5% (WHO low-level threshold) and did not vary statistically significantly overtime. The **Africa Centre's transmitted drug resistance surveillance** among sero-converters identified in the 2010 surveillance round showed a prevalence of **1.39%, 95% CI: 0.25-7.46% (n: 1/72)**. The unique individual had the NNRTI (Y181C) and NRTI (M184V) resistance mutations.

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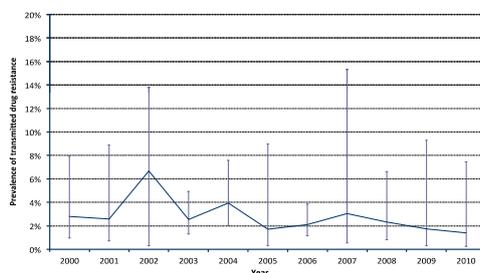


Figure: Trend in the prevalence of TDR between 2000 and 2010.

Poster with complete results at SA AIDS Conference:

Justen Manasa, Sharon Cassol, Chris Seebregts, Marie-Louise Newell, Tullio de Oliveira. 20 years of primary drug resistance studies in South Africa. 5th SA AIDS Conference Poster (P51-47:224)

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HIV drug resistance in first and second line patients in South Africa: EC Free State and Pretoria cohorts.

Introduction:

There has been a lack of effective interaction between South Africa's research and prevention/treatment policies. To facilitate exchange of information between researchers and policy makers, SATuRN, in collaboration with researchers from the United States and Europe, has developed a HIV-1 drug-resistance database. This rapidly expanding database (currently > 2,500 genotypes), which serves a resource for regional and global HIV-1 research, has the capacity to enhance the large-scale systematic monitoring of antiretroviral rollout programs throughout southern Africa.

Results:

Free State 1st line: 116 of 131 (88.5%) patients experiencing virological failure an average of 874 days after the initiation of ART had resistance mutations. NRTI and NNRTI, the most prevalent mutations, were detected in 76.3% and 83.9% of patients, respectively. M184V/I, the most common NRTI mutation, was present in 71.7% of patients, followed by a range of NNRTI mutations (K103N, V106M, G190A, Y181C) present at levels ranging from 43.5% to 17.6%. Although 17.6% of sequences contained TAMs, only 7.6% had more than two TAMs which limit the effectiveness of NRTI's in second line regimens

Data source and Methods:

The database is being populated with a large number of HIV-1 sequences from South Africa and neighboring countries. Researchers in the Free State School (UFS) of Medicine and the Departments of Family Medicine and Immunology at the University of Pretoria (UP) are instrumental in supplying data on patients failing therapy. The UFS and UP component of the database currently consists of two datasets that provide detailed information on the patients' treatment and clinical history, together with the patient's genotypic data.

Pretoria 1st line: Preliminary analysis of 111 patients (113 genotypes) failing first line (NRTI/NNRTI-based) ART indicated that 75.2% of sequences contained at least one NRTI or NNRTI mutation. M184V, the most prevalent resistance mutation, was detected in 71/113 genotypes (62.8%). This was followed, in order of decreasing prevalence, by mutations at K103N (40.7%), V106M (16.8%), G190A (16.8%) and Y181C (13.3%). At least one Thymidine Analog Mutations (TAMs) was detected in 23/111 (20.7%) of patients.



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Free State 2nd line: Resistance mutations were detected in 16/45 (35.5%) of patients experiencing virological failure an average of 714 (interquartile 245-955) days after initiation on to second line ART containing at least one PI. Major PI mutations were identified in only 11.1% of patients. NRTI, NNRTI and TAMs mutations were more common and present at a frequency of 24.4%, 22.2% and 8.9%, respectively.

Pretoria 2nd line: 8/17 (52.9%) adult and 3/33 (9.1%) of children had no detectable resistance suggesting non-compliance. Major PI mutations (V32I, M46L, I47A, L90M) were detected in only of 1/17 (5.9%) adult compared to 7/33 (21.2%) of pediatric patients. 5/33 (15.1%) pediatric sequences contained >3 PI mutations. The most prevalent, M46I and V82A, were detected in 18.2% of sequences followed by I54V, L24I, I50V, L76V at a frequency of 3.0% each. Children also had more NNRTI and NRTI mutations (39.4% vs 29.4%) especially those related to NVP (K103) and 3TC (M184V/I) (27.3% vs 17.7% and 75.8% vs. 29.4%, respectively).

Results to be presented at SA AIDS Conference and IAS 2011:

Van Vuuren C, Goedhals D, Steyn D, Mamabolo MK, Monyane R, Murrell B, Cassol S, de Oliveira T, Seebregts C. Low Level of Protease Inhibitor (PI) Resistance in Patients Failing Second Line Drug Regimens in the Free State Province of South Africa. Poster IAS 2011.

Goedhals D, Van Vuuren C, Steyn D, Mamabolo MK, Monyane R, Murrell B, Cassol S, de Oliveira T, Seebregts C. HIV Drug resistance in adult patients failing first-line antiretroviral therapy (ART) in the Free State Province of South Africa. Poster IAS 2011.

Rossouw T, Mahasha P, Malherbe G, Manasa J, van Dyk G, Cassol S, Seebregts C, de Oliveira T. SATuRN, the Southern African Treatment and Resistance Network: Application to the Management and Surveillance of HIV-1 Drug Resistance in a Public Health Setting in Pretoria. Oral presentation SA AIDS Conference (Session 4, Track , Hall 6, 4-6pm, abstract number 229).

Rossouw T, Malherbe G, van Dyk G, Seebregts C, Feucht U, Cassol S and de Oliveira T for the FIRST HIV-1 Drug Resistance Study Team and SATuRN. HIV-1 Drug Resistance in South Africans Failing Protease Inhibitor (PI)-Based Antiretroviral Therapy (ART): Comparative Analysis of Adult vs. Pediatric Patients. Poster SA AIDS Conference (PS1-26: 230).

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HIV clinical management: Integrating virtually failure clinics in southern Africa.

Introduction:

Several years into the ART rollout program in South Africa some patients are beginning to fail their first- or second-line based drug regimens.

Data on HIV drug resistance and its impact on the management of patients with subtype C viruses is limited. Information on resistance associated mutations at clinical outcome of patients is needed to guide treatment options and ensure that South Africa's ART program is highly effective.

HIV Treatment Failure Clinic Interpretation

Model:

A resistance report is generated using RegaDB/Stanford HIVDB algorithms. The clinical chart and resistance results are interpreted by an Infectious Disease (ID) specialist in Pretoria (Dr. Theresa Rossouw) or Bloemfontein (Dr. Cloete van Vuuren) who suggests the best possible treatment option based on the drugs that are available through the Department of Health in South Africa. The report is sent to the physician managing the patient, who can communicate with the I.D. specialist for further discussion.

HIV Drug Resistance Interpretation:

HIV Drug Resistance Testing Process: RT and protease were sequenced using a discounted in-house genotyping methods, which are freely distributed by SATuRN (more info on this method at page 14 of this report). Data was submitted to SATuRN RegaDB Clinical Database for confirmation of sequence quality and identification of PI, NNRTI and NRTI resistance mutations. A resistance report is produced together with clinical tests and treatment information (an example is seen at page 10 of this report).

Virtual Failure Clinics meetings:

A virtual failure clinic meeting is schedule twice a month on Wednesdays, 8am-9am. During these meetings two clinical cases are presented together with literature on the subject. These meetings are chaired by Dr. Theresa Rossouw (UP), Dr. Cloete Van Vuuren (UFS) and Dr. Kevi Naidu (Africa Centre).



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How to participate in the virtual failure clinics:

These meetings are targeted at clinicians, clinical virologists, researchers and post-graduate students who are currently involved in the treatment of patients with ARVs in Southern Africa. Participants need to register with SATuRN in advance and will join via conference call.

- Next meetings:**
- 29 June 2011 (8-9am)
 - 13 July 2011 (8-9am)
 - 27 July 2011 (8-9am)

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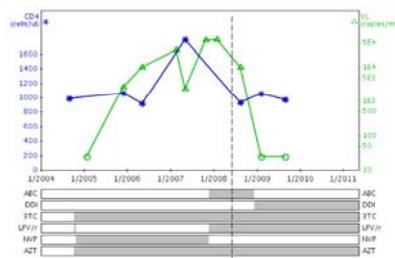
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Example: SATuRN RegaDB Drug Resistance & Clinical Management Report.



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Example: SATuRN RegaDB Drug Resistance & Clinical Management Report.

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Southern African HIV Drug Resistance and Clinical Management Workshop

Introduction:

The Southern African Drug Resistance and Clinical Management Workshop is presented every year.

The workshop includes theoretical lectures and practical sessions on the usage and interpretation of HIV-1 drug resistance genotyping in the management of HIV patients on anti-retroviral (ARV) treatment. This workshop is targeted at clinicians, clinical virologists, nurses, medical students and researchers working in the public and private sector who are currently involved in the treatment of patients with ARVs in Southern Africa.

Notes: This workshop was funded by the European Commission (EC). Treatment Failure Clinic model was funded by the US Centers for Disease and PEPFAR.

Successful past and promising future:

The 4th and 5th workshop was presented on at the University of the Free State (UFS) Medical School in 2009 and 2010.

This workshop, to the best of our knowledge, is now considered the top national meeting on HIV drug resistance and clinical management. In total we have trained nearly 1,000 physicians and nurses as part of this workshop. For example, in 2010 we got 436 applications and 215 participants attended the workshop, representing in total 17 countries. We also had 22 presenters. These include the CDC/PEPFAR Chief of the AIDS Treatment and Care Branch in South Africa, Prof. Jeffrey Klausner, the director of the HIV resistance program from the World Health Organization, Dr. Michael Jordan and some of the top international and national HIV clinicians and researchers.

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See you in Gaborone! The 6th Southern African HIV Drug Resistance and Clinical Management Workshop, 16 to 19 October 2011, Gaborone, Botswana.

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SATuRN and Life Technologies (ABI) partnership to provide a discounted HIV resistance genotyping system.

Introduction:

Antiretroviral (ARV) drugs are becoming increasingly available to treat HIV-1 infected individuals in the developing world. The goal of many governments and non-governmental organizations is to sustain effective ARV treatment of > 5 million people in Africa. Pharmaceutical companies are reducing both prices and international trade restrictions on patented drugs to allow more equitable access to essential medicines for AIDS, TB and Malaria. However, the widespread increase of treatment is threatened by the appearance of drug resistance.

Public health and patient benefit may be limited by the increase in selection and transmission of broadly ARV resistant viruses. Drug resistance viruses can currently be identified with genetic sequencing of two HIV-1 genes. However, the price of an individual test using commercial methods (ZAR 2,500 – US\$ 300) makes it too expensive for public health implementation in southern Africa.

Notes: The in-house HIV genotyping system was funded by the European Commission (EC). Treatment Failure Clinic model was funded by the US Centers for Disease and PEPFAR. Satellite

SATuRN HIV Resistance Genotyping

We have developed an in-house HIV resistance genotyping system in collaboration with the Stanford HIV Drug Resistance Database team and it has been internationally validated by the French AIDS Research (ANRS). Our in-house sequences are generated with the Sanger ABI sequencing technology. This process involves the production of cDNA, which is reverse transcribed from the viral RNA. Our in-house genotyping test currently costs around ZAR 750 (US\$ 100) per sample, a great part of the cost of which (ZAR560/ZAR750) is due to the cDNA synthesis and the ABI sequencing process. As part of this letter, we would like to ask ABI to reduce the price of the reagents needed for HIV drug resistance genotyping for the members of the SATuRN network.

Life Technologies (ABI) and SATuRN partnership:

Life Sciences has agreed to provide 25% discount for reagents for HIV genotyping to SATuRN members. This partnership aim to produce an 'discounted genotypic test kit' to southern African partners that will be available soon. For the moment, partners can request discounted reagents from ABI and the protocol and validation samples from SATuRN partners at the UPS and Africa Centre.

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Acknowledgements

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Coordinating Centre:

Africa Centre for Health and Population Studies – Dr. Tulio de Oliveira.
South African Medical Research Council – Prof. Chris Seebregts.

Collaborators:

Dr. Ashraf Grimwood, CEO, Khethi'Impilo, South Africa.
Dr. Ava Avalos, Dr. Tendani Gaolathe, Dr. Madisa Mine, Botswana Ministry of Health and Botswana/Harvard Partnership.
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Dr. Cloete van Vuuren, Dr. Dominique Goedhals, Dr. Dewald Steyn, Medical School, University of the Free State, South Africa.
Dr. Diana Dickinson, private clinician, Gaborone, Botswana.

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Dr. Gillian Hurt, National Institute of Communicable Diseases, Johannesburg, South Africa.
Dr. Ricardo Jorge Gonçalves Ornelas Camacho, Instituto de Higiene e Medicina Tropical, Universidade Nova de Lisboa, Portugal.
Dr. Soo-Yon Rhee, Tommy Liu and Prof. Robert Shafer, Stanford University, USA.
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Collaborators:

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Prof. Lynne M. Webber, Head of Department of Medical Virology, University of Pretoria, South Africa.
Prof. Rami Kantor, Brown University, USA.
Prof. Robin Wood, Prof. Catherine Orrell, Desmond Tutu HIV Centre, University of Cape Town, South Africa.
Prof. Sharon Cassol and Dr. Theresa Rossouw, University of Pretoria, South Africa.
Prof. Thumbi Ndung'u and Dr. Michelle Gordon, HIV Pathogenesis Programme, Doris Duke Medical Research Institute, University of KwaZulu-Natal, South Africa.

Secretariat:

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Publications & Abstracts:

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- Huang KH, Goedhals D, Fryer H, van Vuuren C, Katzourakis A, de Oliveira T, Brown H, Cassol S, Seebregts C, McLean A, Klenerman P, Phillips R, Frater. Prevalence of HIV type-1 drug associated mutations in pre-therapy patients in the Free State, South Africa. (2009) *Antivir Ther*, 14(7):975-984.
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- de Oliveira T, Gordon M, Cassol E, Murrell B, Seebregts C, Bland R, Newell ML, Cassol S. Use of Selection Pressure Analysis for the Surveillance of HIV-1 Drug Resistance. *Retrovirology*, submitted.
- Manasa J, Cassol S, Seebregts C, Newell ML, de Oliveira T. Tracing twenty years of primary drug resistance studies in South Africa. *AIDS Research and Human Retrovirus*, submitted.

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Publications and Abstracts:

- Manasa J, Cassol S, Seebregts C, Newell ML, de Oliveira T. Tracing twenty years of primary drug resistance studies in South Africa. 5th SA AIDS Conf, Durban, South Africa.

- Van Vuuren C, Goedhals D, Steyn D, Mamabolo MK, Monyane R, Murrell B, Cassol S, de Oliveira T, Seebregts C. HIV Drug resistance in adult patients failing first-line antiretroviral therapy (ART) in the Free State Province of South Africa. IAS 2011, Rome, Italy.

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