Dear Colleagues,

Greetings!

This issue of the YRG CARE Bulletin features two interesting review articles. The first being HIV Resistance Response Database Initiative (RDI)’s treatment decision-making tool which is a novel approach to predict virological response to antiretroviral therapy. With the encouraging set of data generated from RDI’s tool recently, this model approach could possibly be very useful in resource-limited settings. The second review article is on IPAQST, a new Indian initiative to improve TB diagnosis. This highlights the role of IPAQST in addressing the problem of suboptimal diagnosis of TB in India by improving access to the availability and affordability of WHO-endorsed tuberculosis tests.

It is heartening to know of the second baby from Los Angeles, born with HIV that had also shown remission following similar intervention, as with the ‘Mississippi baby’. Looking forward to having more insights in this direction and a possible breakthrough for HIV cure.

I thank all the speakers of the 2nd International Science Symposium on HIV & Infectious Diseases, for having made this event a successful one. My heartfelt thanks to the keynote speaker, Prof. Françoise Barré-Sinoussi and distinguished speakers from NIH, Dr. Jack Whitescarver and Dr. Carl W. Dieffenbach. My special thanks are due to the International AIDS Society, Geneva for co-organizing “HIV Cure” session.

I hope you find this issue of Bulletin interesting and informative.

Sincerely

Prof. Suniti Solomon, MD, FAMS
Editor-in-Chief

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A World of HIV Treatment Experience Freely Available at the Click of a Mouse

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HIV therapy has come a long way in the last quarter of a century. If healthcare resources are not limited, then most patients now enjoy a remarkably positive prognosis. This is being achieved through the use of highly active combinations of antiretroviral drugs, regular viral load monitoring to detect if the drugs are no longer achieving viral suppression and genotyping to detect viral mutations associated with drug resistance and help select the next highly active combination of drugs for the individual [Thompson MA et al., 2012; Williams I et al., 2012].

However, in many settings, resources are limited, to an extent that poses a number of threats to the long-term success of antiretroviral treatment [WHO, 2013]. Many of the newer, more effective and tolerable drugs may not be available. Genotypic resistance testing is often not available or unaffordable so cannot be used to help individualise drugs following failure. Therapy failure is often detected late because of the infrequency or absence of viral load testing, which facilitates the development of resistance, compromising future treatment responses [Hosseinipour MC et al., 2009; Sigaloff KCE et al., 2011, Zhou J et al., 2010; Keiser O et al., 2011; Barth RE et al., 2012].

The lack of monitoring and diagnostic tools to finesse the use of a limited range of drugs means that many physicians do not have the technical means to optimise therapy on an individual basis. Faced with these considerable challenges, the WHO has promulgated a public health approach to therapy, including simple protocols for first and second line therapy and guidance for third [WHO, 2013]. This is in stark contrast to the individualised approach to HIV management in high income countries [Thompson MA et al., 2012; Williams I et al., 2012].

The HIV Resistance Response Database Initiative (RDI) is a global not-for-profit research collaboration established in 2002 with the aim of using bioinformatics to optimise and individualise the use of antiretroviral therapy. Our approach is to use computational models trained with data from thousands of patients treated in clinics around the world to predict virological response to combination antiretroviral therapy [Larder BA et al., 2002]. In effect, distilling millions of patient-years of experience and making it available to physicians around the world.

As of October 2013, data from approximately 110,000 patients have been collected and significant progress has been made in terms of the development of accurate models. The information used to train the models are the viral load, CD4 count and, where available, the genotype, taken while a patient is still on their failing therapy, plus the treatment history, drugs in the new regimen and the viral load after it is introduced (up to a year later). This set of data is called a treatment change episode (TCE) (Figure 1).
The Treatment Change Episode (TCE)

The RDI’s models are available for use, free of charge, as part of the HIV Treatment Response Prediction System (HIV-TRePS) at https://www.hivrdi.org/treps/. The system has been designed to provide the maximum clinical utility to the healthcare professional user. The user enters the values of CD4 count and viral load and the antiretroviral drugs used in the past by the patient. Unavailable or poorly tolerated drugs can be ruled out on an individual or default basis. Genotypic information can also be entered, but it is not mandatory. The user can obtain predictions of the probability of virological response (follow-up viral load <50 copies/mL) for any regimen that they define, and/or for more than a hundred alternative regimens in clinical use around the world. A report is presented to the user in a matter of a minute or less, which lists the five alternative regimens with the highest probability of response, plus any user–defined regimens, ranked in order of the probability of response (Figure 4).

Local therapy costs can be added to the system and it can be used to identify potentially effective regimens within a certain budget. A recent retrospective study using data from a cohort in India found the system was able identify regimens that were more likely to work than those used in the clinic at substantially less cost, for the majority of cases [Revell AD et al., 2013]. The development of these models, which has been pursued and refined for over ten years, involving dozens of studies and hundreds of thousands of TCEs from clinics throughout the world, has produced a system that has enormous potential for supporting the effective salvage treatment of HIV infection, particularly in settings with limited resources where genotypic resistance testing is not available. The level of accuracy achieved means many cases of failure could potentially be avoided, with substantial personal, financial and public health benefits.

Figure 1: The Treatment Change Episode (TCE)
The models have achieved predictive accuracy (measured primarily as the area under the receiver operator characteristic curve) in excess of 80% (Figure 2) and have proved significantly more accurate predictors of response than genotypic resistance testing [Larder BA et al., 2006; Revell AD et al., 2011; Frenetz et al., 2010]. In open prospective clinical studies of the models, highly experienced HIV clinicians evaluated the system as being a useful treatment decision-making tool and changed around one-third of their treatment decisions following use of the system [Larder BA et al., 2011].

Figure 2: Typical ROC curve* from a high-performing model during cross validation [Revell AD et al., 2011]

* Receiver-Operator characteristic curve. Hypothetical perfect prediction shown in the black line, chance prediction (50% accuracy) in the dotted line and the model’s performance in blue

Having established the accuracy and potential clinical utility of the approach, the models were made freely available over the Internet in 2010.

With the intention of helping physicians working in settings where genotypic resistance testing is not available, in 2013 a new set of models were trained that do not require a genotype for their predictions using our largest training data set so far (22,500 TCEs), including more than 1,000 from resource-poor settings in southern Africa. The results were extremely encouraging in that the models achieved approximately 80% accuracy during independent testing [Revell AD et al., 2014]. Moreover, in a subset of patients who had a genotypic resistance testing, the models, operating without the genotype, were significantly more accurate predictors of outcome than genotyping with interpretations systems commonly used in western countries, including the Stanford HIV drug resistance database, the French National Agency for AIDS research (ANRS) and the Rega database (Figure 3).

In addition, for most of the therapy failures, the models were able to identify alternative simple regimens, comprising only those drugs that were available in each clinic at the time, that were predicted to be more likely to result in virological response than the regimen that was used in the clinic.

Figure 3: ROC curves for RF models tested with a global test set (n=1000), southern African cases (n=100) and GSS using three common interpretation systems (ANRS, Stanford HIVDB and REGA)

The RDI’s models are available for use, free of charge, as part of the HIV Treatment Response Prediction System (HIV-TRePS) at https://www.hivrdi.org/treps/. The system has been designed to provide the maximum clinical utility to the healthcare professional user. The user enters the values of CD4 count and viral load and the antiretroviral drugs used in the past by the patient. Unavailable or poorly tolerated drugs can be ruled out on an individual or default basis. Genotypic information can also be entered, but it is not mandatory. The user can obtain predictions of the probability of virological response (follow-up viral load <50 copies/mL) for any regimen that they define, and/or for more than a hundred alternative regimens in clinical use around the world. A report is presented to the user in a matter of a minute or less, which lists the five alternative regimens with the highest probability of response, plus any user–defined regimens, ranked in order of the probability of response (Figure 4).

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Figure 4: Example of HIV-TRePS report
References


Hosseinipour, MC, et al., AIDS. 2009; 23(9):1127-34.


Larder, BA, et al., 13th CROI 2006; Abstract no. 653.


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IPAQT - A New Indian Initiative to Improve TB Diagnosis

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India’s tuberculosis diagnostic landscape changed suddenly in June of 2012 when the Indian Ministry of Health and Family Welfare, acting on the 2011 World Health Organization (WHO) policy against serological, antibody-based TB tests, banned the use, import, sale, and manufacture of these tests, and discouraged the use of latent TB tests like “TB Gold” and “TB Platinum” for active TB.

This ban in 2012 was the first time such action had been taken by the Indian government and it had a major impact in reducing the use of inaccurate blood tests in the country. However, the ban on serological tests had resulted in a void in the market and it became important to address this gap and make sure that WHO-approved, high quality, sputum-based TB tests replace the inappropriate blood tests in the private sector. The private sector in India manages over 50% of all TB cases, and even poor patients seek private healthcare.

There are four accepted sputum tests that are recommended by the WHO and these are also used by the Revised National TB Control Programme (RNTCP). These are sputum smear microscopy, Xpert MTB/RIF (GeneXpert), line probe assay, and liquid cultures. If private doctors and laboratories replace suboptimal tests with the above sputum tests, this should greatly help improve the accuracy of TB diagnosis for patients in India.

However, a big challenge is that high-quality tests like GeneXpert, line probe assay and liquid culture are very expensive in the private sector. For example, the GeneXpert test can cost the patient as much as ₹3500 or even higher in private laboratories. This is because WHO-endorsed tests are not available at specially negotiated low prices to the private sector and customs duties also inflate the costs. In addition, margins by doctors and laboratories further add to the costs to make them virtually unaffordable to the average patient. High cost of WHO-approved tests means that they cannot easily replace the banned serological tests that were cheaper.

Thanks to a new initiative launched in April 2013, aimed to improve the affordability of WHO-endorsed TB tests, the landscape has changed again. Initiative for Promoting Affordable, Quality TB tests (IPAQT; www.ipaqt.org) is a consortium of private labs, supported by industry and non-profit groups (e.g., Clinton Health Access Initiative, McGill International TB Centre), that has made several WHO-endorsed tests available at affordable prices to patients in the private sector.

The business model of IPAQT is based on a shift from high margin low volume (premium) model to lower margin high volume (mass-market) pricing. IPAQT member laboratories get test reagents and instruments at the same price as the public sector. In return, private laboratories have agreed to not exceed negotiated, ceiling prices to patients. They have also agreed to notify all TB cases to the government, participate in external quality assurance, and avoid offering serological TB tests. In exchange for offering lower prices, diagnostic companies and distributors benefit from greater volumes from the previously untapped private market.

Thanks to this initiative, the cost of Xpert MTB/RIF is now reduced to ₹2000 (maximum price labs can charge patients). The line probe assay (Hain Genotype MTBDRplus Version 2) is now available at ₹1800. MGIT liquid culture is now available for ₹900 for detection. These prices are approximately 30 to 50% less than the private market prices before IPAQT was launched, and the prices are comparable to the banned TB ELISA tests. Thus, for the money patients were paying for serological tests, they can now get high-quality tests.

Any laboratory can join IPAQT, provided they have accreditation (e.g., NABL, CAP, RNTCP) and agree to abide by the guiding principles of IPAQT. Laboratories that join IPAQT must agree to stop doing TB serology and avoid promoting tests (e.g., IGRAs) that are discouraged by the RNTCP.

Since its launch in April of 2013, the IPAQT initiative has already achieved a pan-India presence-with 64 labs which encompasses over 3000 franchisee labs and greater than 10,000 collection centers committed to providing these tests at affordable prices. The number of labs is expected to increase greatly in the months ahead. The IPAQT initiative has already received international attention as an interesting model to engage private laboratories in TB control, with coverage in Wall Street Journal, BMJ, UNITAID, Times of India, and the WHO Global TB Report.

For more information on the IPAQT initiative, please visit: http://www.ipaqt.org/
**RESEARCH HIGHLIGHTS**

**Computerized Counseling for HIV Care**

Kurth et al from New York University College of Nursing, New York, USA evaluated a computerized intervention for antiretroviral therapy (ART) adherence and HIV transmission prevention. The study is a randomized clinical trial, involving 240 HIV-positive adults on ART and of which, 209 participants completed nine-month follow-up visit with about 87% retention. The main study outcomes measured include: HIV-1 viral suppression, self-reported ART adherence and transmission risks. The study revealed intervention participants had reduced plasma viral load and significant difference observed in ART adherence. And also their sexual transmission risk behaviors decreased significantly. [Kurth AE et al. J Acquir Immune Defic Syndr. 2013. © Wolters Kluwer, USA].

**Combination ART Effectively Combat HIV Cell-to-Cell Transmission**

Agosto et al from Yale University School of Medicine, Connecticut, USA have demonstrated that some NRTIs are less effective against HIV-1 cell-to-cell transmission and that most NNRTIs, entry inhibitors and protease inhibitors remain highly effective. Interestingly, the study observed that poor NRTIs become highly effective when applied in combinations explaining the effectiveness of ART in clinical settings. [Agosto LM et al. PLoS Pathog. 2014; 10 (2): e1003982. © Public Library of Science, USA].

**HCV: Longevity of Infectivity Revealed**

Paintsil et al from Yale School of Medicine, USA had evaluated the infectivity of HCV after keeping the dried biospecimen (plasma / serum) spots at 3 different temperatures (4°C, 22°C, and 37°C) for up to 6 weeks. The viral infectivity was measured using a microcoture assay. The viable HCV was recovered from the low-titer spots for up to 6 weeks of storage at 4°C and 22°C. The infectious HCV was recovered only up to 7 days of storage at temperature of 37°C. [Paintsil et al. J Infect Dis. 2014;209(8):1205-11. © Oxford University Press, UK].

**HIV Patients at Greater Risk for Heart Attack?**

Post and colleagues from Johns Hopkins School of Medicine, Baltimore, have reported that men with HIV infection are at increased risk for the development of coronary artery disease than HIV-uninfected. This cross-sectional observational study included 618 HIV-infected and 383 uninfected men who have sex with men and aged between 40 to 70 years. HIV-infected men had a greater prevalence of coronary artery calcium with the prevalence ratio of 1.21 [Post et al. Ann Intern Med. 2014; DOI:10.7326(M14)-1754. © American College of Physicians, USA].

**Molecular Scissors to Snip HIV**

Tebas et al from the University of Pennsylvania have conducted a first-of-its-kind study with gene editing approach in humans. In this phase I study with 12 HIV positive patients, using Zinc-finger nuclease (ZFN) technology, the CCR5 genes of CD4+ T cells were rendered dysfunctional and the cells infected to the same patients again. The study results demonstrate that this autologous infusion of genetically engineered CD4+ T cells is safe. The study also shows promise in the ability of this approach to suppress the virus, as evidenced by reduced blood level of HIV DNA in most patients and HIV RNA was undetectable in one of the patients evaluated. [Tebas P et al. N Engl J Med 2014; 370:901-910. © NEJM Group, Massachusetts Medical Society, USA].

**NIH Study: New Genetic Mutations Lead to Immune Deficiency**

Zhang et al from National Institutes of Allergy and Infectious Diseases, NIH, Bethesda, have reported a new type of genetic syndrome characterized by severe allergy and immune disorders. The investigators studied 8 patients from 2 families with similar syndromic features and exome sequencing revealed a new disease-causing genetic mutation in them. It was found that the syndrome is caused by mutations in the PGM3 gene that result in the production of underactive PGM3 protein,[Zhang Y et al. J Allergy Clin Immunol.2014;DOI:10.1016/j.jaci.2014.02.013. © Elsevier Inc., USA].

**Ring of Protection: Double Action**

Clark et al from University of Utah, Salt Lake City, USA have designed long-acting drug delivery systems that simultaneously protect women from sexual transmission of HIV and unwanted pregnancy for up to 90 days. This is a dual-reservoir (made out of polyether urethanes) intra-vaginal ring that delivers Tenofovir and the contraceptive 1.3 wt% Levonorgestrel. The device is designed to release an average of 7.5 mg TDF and 21 µg Levonorgestrel per day in vitro for 3 months.[Clark JT et al. PLoS ONE; 2014; 9 (3):e88509. © Public Library of Science, USA].

**Tweet to Thwart HIV?**

Young et al from University of California, Los Angeles, carried out a study to establish methods of using data from real-time social media like Twitter for HIV prevention. The study methodology included extracting geo-located conversations about HIV risk behaviors and studying the prevalence and content of these conversations. The study findings show that it might be possible to predict high risk behaviors by monitoring tweets, mapping the locations from where the tweets originate and linking them with data on the geographical distribution of HIV cases. The study highlights the feasibility of using this cost-effective approach to use the ‘big data’ from social media for remote monitoring and surveillance of risk behaviors and potential outbreaks. [Young SD et al. Prev Med. 2014; pii: S0091-7435(14)00053-3. © Elsevier Inc., USA].

**Vitamin A and Immunity : Mouse Model Study Reveals the Connection**

Spencer et al from NIH, Bethesda, USA, used a mouse model of vitamin A deficiency to examine how malnutrition affects immunity and found that the type 2 innate lymphoid cells (ILC2) subset typically provides immune defense against helminth infections. This study identifies ILCs as sensors of malnutrition that alter gut immunity in response to diet. [Spencer SP et al. Science. 2014; 343(6169):432-7. © American Association for the Advancement of Science, USA].

**Xpert MTB/RIF to Diagnose Extrapulmonary TB?**

Denkinger et al from McGill University, Montreal, Canada and collaborating institutions performed a systematic review and meta-analysis to assess the accuracy of Xpert MTB/RIF assay for detection of extrapulmonary TB. The study included 18 studies involving 4461 samples and the sensitivity differed substantially based on the sample types. When compared against culture, the Xpert pooled sensitivity was 80.5% for cerebrospinal fluid and 83.1% for lymph node tissues or aspirates. Based on this systematic review, the World Health Organization now recommends Xpert over conventional tests for TB diagnosis in lymph nodes, other tissues and as the preferred initial test for TB meningitis. [Denkinger CM et al. Eur Respir J. 2014: DOI:10.1183/09031936.00007814. ©The European Respiratory Society, UK].
The American Conference for the Treatment of HIV (ACTHIV) is a premier conference dedicated exclusively to the clinicians caring for individuals with HIV. The conference delivers information on key newer developments and research findings that can be rapidly translated and applied directly to the clinical setting. Source: https://www.signup4.net/Public/ap.aspx?EID=ACTH20E

CLINICAL TRIAL News

ACTG 5176 Trial: Fruitful Outcome with DermaVir, a Therapeutic HIV Vaccine Candidate

A phase II, randomized, double-blind study evaluated the safety, tolerability, and immunogenicity of a DermaVir vaccine in HIV-1 infected subjects currently under treatment with HAART. Treated HIV-infected adults with HIV RNA <50 copies/mL and CD4 >350 cells/µL were randomized to placebo or escalating DermaVir doses. The immunogenicity was assessed by a 12-day cultured interferon-γ ELISPOT. The study outcome showed that DermaVir vaccine was well tolerated and showed greatest immunogenicity. [Rodriguez B et al. J Acquir Immune Defic Syndr. 2013;64(4):351-9. © Wolters Kluwer, USA].

CAPRISA 004: Breakthrough Microbicide Gel

The CAPRISA 004 Tenofovir gel trial showed proof of concept that an antiretroviral gel used before and after sex can protect against HIV. This double-blind and randomized controlled trial compared Tenofovir gel in 445 women with a placebo gel in 444 women in and around Durban, South Africa. The women participating in the trial were all sexually active and between 18 and 40 years of age. The microbicide gel, containing 1% Tenofovir was 39% effective in preventing HIV infection in women. This microbicide gel has provided additional benefit of preventing genital herpes infections demonstrating more than 50% effectiveness. [http://www.caprisa.org/View/NewsEvents/2/31].

Thibela TB Trial: Mass Isoniazid Preventive Therapy is not Beneficial

The Thibela TB study evaluated whether mass screening and treatment for latent tuberculosis has impact on tuberculosis control in South African gold mines. This was a randomized study with 78,744 miners as either intervention group (n=40,981) or control group (n=37,763). In the intervention group, all miners were offered tuberculosis screening. If active tuberculosis was diagnosed, they were referred for treatment and if not, they were offered 9 months of isoniazid preventive therapy. The intervention did not reduce the incidence of tuberculosis during the 12 months follow up period. The trial concluded that the mass screening and treatment for latent tuberculosis had no significant effect on tuberculosis control. [Churchyard GJ et al. N Engl J Med. 2014;370(4):301-10. © NEJM Group, Massachusetts Medical Society, USA].

Top REVIEW ARTICLES FREE


HIV/STD Guidelines New

WHO: March 2014 supplement to the 2013 consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection; 28 February 2014.

NIH: Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection; 12 February 2014.


NIH: Corrections to the Pediatric Opportunistic Infections Guidelines ; 02 April 2014.


Funding Opportunities / Fellowships

If you are not able to access the hyperlinks we can send you hyperlinks through email on request to bulletin@yrgcare.org.


DST: Call for India-UK Scientific Seminar scheme. Deadline: 10 June 2014.


HIV Research Trust Scholarships. Open date: Sep 2014.

FREE Online CME Courses

HIV, HCV & STD Clinical Education Initiative

The Clinical Education Initiative (CEI) offers FREE online and onsite HIV, HCV and STD trainings to meet the education needs of HIV care providers.

Source: http://www.ceitraining.org/
A Cure for HIV: Dare to Dream? : Online Video

On 19th March 2014, UNAIDS India hosted a seminar at the India International Centre in New Delhi. Prof. Sharon Lewin, Co-Chair of the AIDS2014 Conference, outlined the recent developments in HIV Cure research that have made global headlines over the past few years: examples such as Timothy Brown, the first man cured of HIV/AIDS through a bone marrow transplant and the case of the Mississippi baby who was treated with antiretroviral drugs for HIV immediately after birth and two years since being taken off therapy at 18 months, remains free of HIV. Source: http://www.aids2014.org/Default.aspx?pageId=716

Sun Foundation’s Donation for Laboratory Equipment

Sun Foundation, Chennai, as part of its philanthropic contribution, donated ₹ 6,00,000 towards lab equipment, which will be used for patient care.

Nobel Laureate: (Co-discoverer of HIV) Prof. Françoise Barré-Sinoussi Visits YRG CARE Facility

Prof. Solomon extending a warm welcome to Prof. Françoise B. Sinoussi (Nobel Laureate for HIV co-discovery and President, International AIDS Society) at Voluntary Health Services (VHS) Campus facility on 30th January 2014.

PhD Degree Course

Applications for the PhD degree course in Medical Microbiology (Affiliated to the University of Madras) at YRG CARE are invited from candidates who have passed national entrance tests for independent fellowships such as CSIR /ICMR/ DBT or INSPIRE fellowship. For more details, please write to lab@yrgcare.org.


YRG CARE will be organizing a 3-day workshop on Good Clinical Laboratory Practices (GCLP). International Standards ISO15189:2012 in early 2015 (exact dates will be announced soon) at TICEL Bio-park, Taramani, Chennai. This GCLP workshop will outline the basic principles and procedures to be followed by medical laboratories involved in patient care and/or clinical research. For more details on the workshop, visit the website at http://yrgcare.org/gclp.
YRG CARE conducted a 3-day event, 2nd International Science Symposium on HIV & Infectious Diseases (HIV SCIENCE 2014) on 30th Jan-1st Feb 2014 with 25 international and 14 national speakers. The distinguished speakers of the event include Prof. Francoise B. Sinoussi (Nobel Laureate for co-discovery of HIV and President of International AIDS Society, Geneva), Dr. Jack Whitescarver (Director, Office of AIDS research National Institute of Health USA) and Dr. Carl W. Dieffenbach, Director, Division of AIDS, National Institute of Health (NIH), USA. Totally 461 delegates participated in this meeting including 21 international delegates. The event was accredited by Tamilnadu Medical Council and Tamilnadu Dr.MGR Medical University. The abstracts presented in this symposium were published in the journal, BMC Infectious Diseases.

Prof. Francoise B. Sinoussi lighting the traditional kutthu vilakku marking the inauguration of HIV SCIENCE 2014. Prof. SP Thyagarajan, Dr. Jack Whitescarver and Prof. Solomon look on.


