Asia-Pacific
Economic Cooperation

«HIV vaccines as a part of complex approach to AIDS prevention and control in APEC region»

Final report

Health Working Group
APEC Committee on Economic and Technical Cooperation

Moscow
July, 2012

APEC PROJECT

«HIV vaccines as a part of complex approach to AIDS prevention and control in APEC region»

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CONTENT

a) The Project background

Research in the area of HIV-infection/AIDS has been for more than 30 years the arena of wide international cooperation, where representatives of the fundamental science, specialists in pharmacology, health managers and others are taking part.

The latest epidemiological data indicate that, globally, the spread of HIV appears to have peaked in 1996, when 3.5 million people were newly infected. By 2008, that number had dropped to an estimated 2.7 million. AIDS-related mortality peaked in 2004, with 2.2 million deaths. By 2008, that toll had dropped to 2 million, although HIV remains the world's leading infectious killer. The epidemic appears to have stabilized in most regions, although prevalence continues to rise in Eastern Europe, Central Asia and other parts of Asia, due to a high rate of new HIV infections. Sub-Saharan Africa remains the most heavily affected region, accounting for 72 per cent of all new HIV infections in 2008. However, pandemic continues spread, not recognizing the borders. More than 34 million people were living with HIV at the end of 2010. The number of adult people and children newly infected with HIV is 2.2 million. Most of all HIV pandemic affect young able-bodied population with more than 40% of new HIV infections registered among adults.

This project directly corresponds to the APEC key priorities, since it helps fighting against HIV/AIDS in the APE region and is a follow up of the HWG program of fighting against HIV/AIDS in the APEC region.

In February 2008 (Lima, Peru) HWG meeting declared fighting against HIV/AIDS in the APEC region as area of priority.

In the 2009 APEC Leaders' Declaration, Leaders reaffirmed to build up the ability of regional avian influenza and other potential emergency and sub-emergency disease such as HIV/AIDS and Tuberculosis.

In 2010, one of the priorities cited in the 2010 Health Working Group work plan is "Enhancing preparedness for and response to public health threats, including avian and human pandemic influenza and vector borne diseases and HIV/AIDS".

This project also supports the Action Plan in the APEC Leaders' Growth Strategy since it targets human health and security through withstanding and ultimately overcoming HIV pandemic.

Joint statement of the 22nd Ministerial Meeting welcomed efforts by the Health Working Group to improve the capacity of APEC economies to respond to emerging and re-emerging infectious diseases of pandemic potential.

This project is a direct response to the APEC HWG medium term work plan (2010 – 2015) as it aims at enhancing preparedness for and effective management of emerging and re-emerging infectious diseases, vector-borne diseases, HIV/AIDS and pandemics.

The project was implemented under overseeing of Mr. Rakhim M. Khaitov, Director of the National Research Center – Institute of Immunology of the Federal Medical Biological Agency of the Russian Federation Ministry of Health, the Project

Leader is Mr. Yuriy A. Kalik, Director of International Projects, Borlas Security Systems, Ltd., Moscow, Russian Federation.

b) The Project Objectives

The project «HIV vaccines as a part of complex approach to AIDS prevention and control in APEC region» makes a contribution into the fulfillment of the HWG medium term work plan (2010 – 2015) as it aims at enhancing preparedness for and effective management of emerging and re-emerging infectious diseases, vector-borne diseases, HIV/AIDS and pandemics. This project meets HWG priorities to organize cooperation and to create an expert network in order to provide sustained sharing of expertize in the field of HIV vaccine.

The key objectives of the project were:

- To help APEC economies to enhance information and experience sharing in the field of HIV vaccines development as a part of comprehensive approach in order to formulate more effective AIDS prevention strategies in region
- To help participants to identify the major challenges and constraints in APEC economies' HIV prevention programs and to define the role and place of HIV vaccine development

- To provide a good opportunity for member economies to network. To create favorable conditions for the development of cooperation and business communication between specialists and organizations involved in HIV prevention efforts in order to establish professional and business contacts. Through the expert network the cooperation and coordination among APEC economies will be strengthened

All the objectives of the project were successfully achieved by the project executors.

Three main fields were discussed at the Workshop:

1) The role of HIV vaccines as a part of comprehensive approach to control HIV epidemic in APEC region;
2) Clinical trials. The existing experience in HIV vaccine related isues;
3) Normative/Legislative/Ethical issues.

All the speakers in their presentations and participants during discussions were mentioning, that it is necessary to share the knowledge and information received during the Workshop not only with representatives of APEC member economies within one group, and not just invite, but actively involve other related organizations and communities. Activities, developed on the basis of those organizations, will facilitate cross-border exchange of knowledge and actions, improving the HIV/AIDS status in the APEC region and will make a big contribution into the efficiency of the fight with this dangerous and aggressive disease.

c) Conclusions and follow-up in APEC

Fruitful discussions allowed participants of the Workshop to make conclusion in the following:

HIV infection / AIDS is the life-threatening disease and very important concern of public health in APEC economies, which needs governmental support. It is necessary to improve the strategies of counteraction to this infection. HIV vaccine is the one of the most perspective tools for the control of HIV infection, and it is rationale to expand works on the development of HIV vaccine.

There are different levels of investigations in the field of development of HIV vaccine, capacity building, preparedness for clinical trials and further implementation in APEC economies. It seems rationale to improve sharing of information, research achievements, clinical trials experience. Establishment of international collaboration network in these fields is one of the key factors to support progress in HIV/AIDS counteraction.

Clinical trials are the essential part in HIV vaccine development. Collaboration and coordination between APEC economies are very important to perform international multicentral clinical trials of effectiveness of new candidate HIV vaccines, which in future may be approved for implementation in APEC region. Collaboration in harmonization of normative, legislative and ethical aspects of clinical trials will be strategic mechanism to facilitate the discovery of HIV vaccine for APEC community and ultimately, the global community.

The effect of HIV vaccine is being determined not only by the effectiveness of vaccine itself, but strongly depends on the acceptance of vaccine in population. It is reasonable to support efforts in distribution of information about HIV vaccine safety, properties, investigations in the field of HIV vaccines and other efforts improving the acceptance of HIV vaccines.

Workshop was very useful, all set tasks were fulfilled. Workshop made a good contribution to the member economies in organizing cooperation and in creation of expert network in order to provide sustained sharing of expertize in the field of AIDS prevention, including HIV vaccine development and clinical trials. This, in turn, will promote HIV vaccine implementation and contribute to APEC Human Resources Development Action Plan and ultimately, will promote to halt and reverse the spread of HIV and contribute to the achievement of the Millennium Development goals.

The development of the Workshop theme «HIV vaccines as a part of complex approach to AIDS prevention and control in APEC region» should be continued and include the organizing of cooperation in different APEC economies, fora, international organizations and creation of the experts network in order to provide sustained sharing of expertize in the field of AIDS prevention, including HIV vaccine development and trials.

d) The Workshop Administrative Circular

Ministry of Public Health and Social Development of the Russian Federation
Federal Medical-Biological Agency (FMBA of Russia)
National Research Center the Institute of Immunology of the FMBA of Russia

APEC Workshop

HIV vaccines as a part of complex approach to AIDS prevention and control in APEC region

Administrative Circular

Information and Guidelines

Moscow, Russian Federation
4-5 July, 2012

TABLE OF CONTENTS

1. INTRODUCTION

This Circular provides administrative, logistical and general information for the APEC Workshop "**HIV vaccines as a part of complex approach to AIDS prevention and control in APEC region",** Moscow, Russian Federation

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- **2 MEETING DATES AND VENUE**

Date: 4-5 July, 2012 (Wednesday to Thursday)

Venue: Hotel "Cosmos"

Hall "Neptun"
Direction indicator boards will be on the right side of the hotel Lobby

Address: 150, Prospect Mira, Moscow, Russia
Metro station "VDNH"

Phone: + 7(495) 234-12-06
www.hotelcosmos.ru

Official Language: English

3. DRAFT AGENDA

Please see **Annex A** for the draft agenda**.**

- **4. CONTACTS**

Project Overseer: Khaitov, Rakhim Musaevich
Director, National Research Center - Institute of Immunology of the Federal Medical Biological Agency
24 Kashirskoye Shosse, building 2, 115478 Moscow, Russian Federation

Contact persons:

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Ms. Nataliya Makarycheva	nmakarycheva@borlas.ru	Tel.: +7(903) 244-77-66
Mr. Yuriy Kalik	ykalik@borlas.ru	Tel.: +7(967) 221-76-82

Tel: +7(499) 617-78-44
Fax: +7(499)617-10-27

Workshop organizing committee:
goudima@gmail.com
nikolaeva.immune@mail.ru
nmakarycheva@borlas.ru
ykalik@borlas.ru

5. REGISTRATION

- ***5.1. Registration Procedure***

All delegates are to be registered for the Workshop using the registration form (see Annex B).

All completed registration forms should be submitted to organizer to the following addresses:

goudima@gmail.com nmakarycheva@borlas.ru
nikolaeva.immune@mail.ru ykalik@borlas.ru

by 23 June 2012.

- ***5.2. Registration at the Workshop venue and ID Badges***

The Registration Desk will operate in the hall of "Cosmos" hotel

Wednesday, 4-th July, 2012 10.00AM – 11.00AM

All delegates can collect their ID badges at the Registration Desk. The ID badges should be worn at throughout the whole Workshop and will be required for entry into the Workshop venue.

- ***5.3. Dress Code***

Delegates are advised to dress in smart casual.

5.4 Visas and Customs Information

For entry into the Russian Federation a visa is required. The procedure for obtaining a visa is standard. The participants are advised to refer to the Embassies and Consulates of Russia in their economies for visas in advance**.** Visa requirements to enter Russia can be found in **Annex C.**

Participants should take into account that for applying for visa to Russia it is necessary to complete online accreditation as soon as possible since processing of such visa applications requires about two weeks.
When applying for visa a delegate needs to provide the letter of confirmation e-mailed to participants from the accreditation portal upon registration, and notify our consular officer that he/she is coming to APEC events in Moscow, Russia and that respective authorization from Moscow will be sent via official channels (the basis for such authorization is filled-in accreditation form).

To get visa support from relevant Russian authorities, the participants of the Workshop should send to the organizers beforehand by e-mail:

goudima@gmail.com nmakarycheva@borlas.ru
nikolaeva.immune@mail.ru ykalik@borlas.ru

- scan copy of the international passport

- place of work. Position, address, phone No., fax No.

All foreign citizens arriving to the Russian Federation need to undergo customs control. When passing through the green channel the customs declaration is optional. Customs

declaration forms which will be provided by the airline staff before landing are required to be filled in by those participants who bring in cash in excess of 10,000 USD or goods that are subject to customs clearance.
Inquiries related to customs control may also be directed to visa@apec2012.ru

5.5 Baggage and Item Restrictions

Airlines operating in the Russian Federation strictly enforce baggage size and weight limitations, and ***participants are requested to familiarize themselves with their airline weight and carry-on restrictions prior to traveling in order to avoid extra fees or complications.*** Inside the check-in area, the participants can use the baggage packing service.
In addition, for the sake of airline security some articles and substances must not be carried aboard.

• 6. DOCUMENTATION

All documents should be submitted in soft copy to:
The workshop organizing committee at: goudima@gmail.com, nikolaeva.immune@mail.ru, nmakarycheva@borlas.ru and ykalik@borlas.ru at your earliest convenience **before 23, June 2012.**

Delegates should provide detailed instructions if there are any special requests on the reproduction and distribution of the document(s). The deadline for document submission is **23 June 2012.**

7. ACCOMMODATION

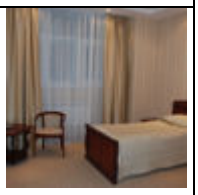
For the convenience of the delegates there are hotels offered for stay as follows:
Hotel “Cosmos” 150, Prospect Mira, Moscow, Russia (Preferable)/

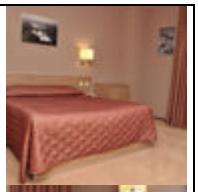
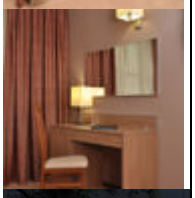
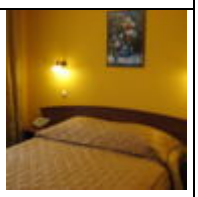
Phone: + 7(495) 234-12-06
Reservation:
Tel.: (495) 234 12 06
Fax: (495) 234 24 63
E-mail: reservations@hotelcosmos.ru

Standard single room cost – 3600/4100 rubles with breakfast and VAT.
Exchange rate for 17/06/2012 – 32,39 rubles for 1 dollar.
Relevant information about the currency exchange rate can be found at http://www.cbr.ru/eng/daily.aspx

Other hotels. located near “Cosmos” hotel:

Hotel name booking.com			English	Foto
Oksana Hotel *Yaroslavskaya Street 15 Bld. 2, 129366 Moscow* http://www.booking.com/hotel/ru/oksana.ru.html?sid=d3fec959cb61d78f61c5915	***RUB 3600.00***		Oksana Hotel is set in a quiet neighborhood, within a 5 minute walk of the Metro, the Russian convention center, and the Cosmos casino. Energize at the fitness center, enjoy a game of mini-golf, or take a short walk down to the Space Museum and park. The efficient staff can help	

a148428e5;dcid=1			with tourist information. Hotel Oksana is fully equipped for business guests, with 9 conference rooms. These cater for between 10 and 100 persons. The reception area and interiors are well equipped for welcoming colleagues or friends. Enjoy tasty European cuisine at the restaurant. Follow the meal with a favorite drink at the cozy bar.	
TIPO Hotel *Prospekt Mira 105, 129085 Moscow* http://www.booking.com/hotel/ru/tipo.ru.html?sid=d3fec959cb61d78f61c5915a148428e5;dcid=1	**RUB 3360.00**		Less than half a mile from Tikhvin Church, this 3-star hotel in Moscow offers modern spa facilities, spacious rooms with flat-screen TV, and free Wi-Fi. VDNH Metro Station is 1700 ft away. A hammam with Russian banya and solarium awaits guests at the Tipo Hotel. Different massages and beauty treatments can be enjoyed here. All air conditioned rooms at the Tipo feature classical-style furniture, a minibar, and a desk. Each bathroom includes a corner bathtub. Breakfast is available at the Hotel Tipo. Traditional Russian food is served in the restaurant. The All-Russia Exhibition Center is less than one mile from the Tipo Moscow. Private parking is available at the Tipo upon request.	

D'Hotel *Yaroslavskaya Street 8/8, 129164 Moscow* http://www.booking.com/hotel/ru/de.ru.html?sid=d3fec959cb61d78f61c5915a148428e5;dcid=1	***RUB 3119.00***		This 10-story building houses a comfortable hotel in Moscow's business district, with the nearest metro station just a short walk away. Enjoying quiet, green surroundings, D'Hotel is a great base for exploring Russia's capital. Start the day with breakfast in bed. After checking your email via free wireless internet, you can make your way to the center of the city. D'Hotel stands for comfortable accommodations and friendly service. Relax in your spacious room or pay a visit to the restaurant. The lobby is open 24 hours per day, enabling you to come and go as you please. Business travelers will especially appreciate the desk in each room. Prepare a meeting with the help of the attentive staff. Room service is also available at D'Hotel.	  
VashOtel - Zolotoy Kolos *Yaroslavskaya Street 10 Bld 2, 129366 Moscow* **http://www.booking.com/hotel/ru/zolotoy-kolos.ru.html?sid=d3fec959cb61d78f61c5915a148428e5;dcid=1**	***RUB 3600.00***		Zolotoy Kolos is just a 20-minute walk from the All-Russia Exhibition Centre and a 10-minute walk from the VDNKH Metro Station. It features a restaurant and a 24-hour reception. Guests can enjoy a varied breakfast buffet every morning at the Zolotoy Kolos Hotel. Russian and international cuisine are served in the restaurant. Rooms at the Kolos Zolotoy Hotel are classically furnished, and have a TV and refrigerator. The en suite	

			bathrooms include toiletries. Moscow city centre is a 20-minute drive from the hotel. The famous Cosmonauts Alley and the Monument to the Conquerors of Space are just a 5-minute walk away.	
Derzhavnaya Hotel *Yaroslavskaya Street 8 Bld.2, 129164 Moscow* **http://www.booking.com/hotel/ru/derzhavnaya.ru.html?sid=d3fec959cb61d78f61c5915a148428e5;dcid=1**	***RUB 3900.00***		This Moscow hotel offers free Wi-Fi, massage facilities and a sauna. Central Moscow and Red Square are less than 15 minutes away by metro. The traditional rooms at the Derzhavnaya Hotel offer simple and bright furnishings. Every room comes with tea and coffee facilities, cable TV and an electric kettle. A buffet breakfast is served in the contemporary-style Cafe Sonata on the hotel's ground floor. In the summer, guests can enjoy drinks and food on the cafe's shaded outdoor terrace. Derzhavnaya Hotel is a 5-minute walk to the VDNK Metro Station and the picturesque Cosmonauts Alley pedestrian walkway. The All-Russia Exhibition Centre is 4.5 km away. Kazansky Rail Station is 9 km from the hotel, while Sheremetyevo Airport is located 40 km away. An airport shuttle and secure valet parking are available.	 
Cosmos Hotel ***Prospekt Mira 150, 129366 Moscow***	***RUB 3750.00***		Located next to the All-Russia Exhibition Centre, this 4-star hotel offers an indoor pool, a spa with massage	

http://www.booking.com/hotel/ru/kosmos.ru.html?sid=d3fec959cb61d78f61c5915a148428e5;dcid=1;checkin=2012-07-04;checkout=2012-07-05;srfid=350fa7a0a93996a2398fbacc0f766338X9			services and a modern gym. VDNKh Metro Station is 400 metres away. The colourful rooms at the Cosmos Hotel have Wi-Fi access, a flat-screen TV with satellite channels, and a refrigerator. Toiletries and a hairdryer are provided in the private bathrooms. There are 10 restaurants and cafés at Cosmos Hotel, all with free Wi-Fi. Planet Cosmos restaurant serves Russian and European cuisine and offers views of the Moscow skyline from the 25th floor. An American-style breakfast is served in the Kalinka restaurant. Guests can also enjoy Mediterranean dishes in the Il Gusto restaurant, and Chinese meals and karaoke in the Happy Land restaurant.	

Costs are given in Russian Rubles
Exchange rate for 17/06/2012 – 32.39 rubles for 1 dollar.

Room reservations and all modifications in booking must be made within the reservation period. Please be advised that deadlines for making room reservations at each of the designated hotels might vary one from the other. Please pay attention to the reservation period stated in the table below. After reservation period is over the special APEC rate package may no longer be available.

Participants are responsible for all room costs, upgrades and other charges.

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- **8. TRANSPORTATION AND AIRPORTS**

Delegates are responsible for arranging their own transportation from/to the airport and the hotel as well as from/to the meeting venue and the hotel. The Domodedovo International Airport, Vnukovo International Airport and Sheremetyevo International Airport are about 30 km, or approximately 1 hour by car, from the vicinity of the meeting venue/city centre. Taxi fare costs around USD 100. Delegates are to note that varying fees may apply eg. peak hour and electronic road pricing surcharges, depending on the time of boarding and route taken. Delegates may also wish to use rail way from Airport Sheremetyevo to Belorusskaya Subway Station, from Airport Domodedovo to Paveletskaya Subway Station, from Airport Vnukovo to Kievskaya Subway Station; 60 min, 15 USD.

Moscow Airport Information

There are three airports in the city of Moscow. Participants will arrive at Sheremetyevo Airport, Domodedovo Airport or Vnukovo Airport, depending on the flight route. Participants are encouraged to clarify information on the terminal of arrival with their airline company.

Name of the airport	Call-center	VIP hall
Sheremetyevo Airport http://www.svo.aero/en/	Tel: +7 (495) 578 65 65	Tel: +7 (495) 981-09-09
Domodedovo Airport http://www.domodedovo.ru/en/	Tel: +7 (495) 933 66 66	Tel: +7 (495) 967 84 62
Vnukovo Airport http://vnukovo.ru/eng/index.wbp	Tel: +7 (495) 937 55 55	Tel: +7 (495) 436 80 18

8.1 Public Transportation and Taxi

It is highly recommended to use taxi cabs only with special taxi service insignia. Delegates can order a taxi in advance from their hotel.

8.2 Individual Transportation

You can always rent a car with a driver.

Type of a Vehicle	Approximate Travel Fare
Minivan for 6 to 12 persons	from 1380 RUB per hour depending on the brand
Executive car (Mercedes, BMW, Audi)	from 1680 RUB per hour depending on the brand
Business car (VW, Nissan, Toyota)	from 1380 RUB per hour depending on the brand
Bus for excursions for up to 50 passengers	from 1600 RUB per hour depending on the brand

9. FUNDING

According to the APEC guidelines, APEC will cover the travel expenses (i.e. airfare and .per diem) for a maximum of two participants from each APEC travel-eligible economy (Chile, People's Republic of China, Indonesia, Malaysia, Mexico, Papua New Guinea, Republic of the Philippines, Peru, the Russian Federation, Thailand and Vietnam).
Participant(s) from travel-eligible economies who wish to seek APEC funding for their travel expenses (airfare + per diem) should submit an airfare quotation to:

1. **APEC Secretariat**, attention **Ms. Mary Tan** at mt@apec.org

Unless there is a request for advance payment, funding for all approved participant(s) and expert(s) will be made after the event.
For request for advance payment, please email to the APEC Secretariat (Attention: **Ms Mary Tan** at mt@apec.org) by **23 June 2011** together with airfare quotation.

All APEC funded travelers are required to complete a travel undertaking at least 8 working days before travel commences. Travelers will not be reimbursed if the travel undertaking is not completed prior to travel.

If your economy wishes to send more than the approved number of participants, the expenses for the additional participant will be borne by your economy.

Participants from other economies (up to 8 participants) are invited to attend the workshop on a self-funding basis.

- **10. FACILITIES**

Broadband Internet connection at specified locations within the meeting venue, computers, printers, facsimiles and photocopiers will be available at the venue of the workshop.

- **11. GENERAL INFORMATION**

11.1 Weather

June predictably experiences the warmest and most humid climate in Moscow, when temperature often stays around 23°C / 73°F during the daytime, and at times rises even a little higher. Sunrise is about 4:00, sunset is about 22:30.

11.2 Time

Time zone of Moscow is UTC/GMT +4.

11.3 Tipping

Tips are on average 10% of the total amount but may depend on the quality of the provided service. In restaurants it is common to leave 10% of the total amount. Tips of 30-70 RUB (1-2 USD) per bag are customarily given to baggage handlers at airports and hotel bellhops who take luggage to a guest room. It is also customary to tip hotel room cleaning staff 30-70 RUB per day (1-2 USD).

11.4 Electricity and Water Supply

The supply voltage in Russia is 220 volts. It is desirable to boil tap water before drinking. We also advise the participants to consume bottled water which can be purchased at the hotel or any nearby grocery store.

11.5 Smoking

In Russia, there is no general prohibition on smoking in public areas. Bars and restaurants are divided into smoking and nonsmoking zones. Inside theaters, museums and other cultural or educational institutions smoking is prohibited (with designated areas usually provided for smokers).

11.6 Useful Telephone Numbers

Emergency (for subscribers of mobile networks): 112
City emergency services:
Emergency: 01
Police: 02
Ambulance: 03

Dialing Russian numbers from outside Russia:
Please dial telephone numbers as indicated: country code (+7), area code (495 or 499), telephone number (7 digits)

Dialing Russian numbers from your mobile phone during your visit to Russia:
Please dial telephone numbers as indicated: country code (+7), area code (495 or 499), telephone number (7 digits)
Always dial country code, area code and telephone number when area code is different to 495 or 499.

Dialing international telephone numbers from your mobile phone during your visit to Russia:
Please use international standard procedure: dial "+", country code, area code, telephone number.

When making a phone call from the fixed telephone at your hotel room – please follow instructions or ask concierge service for help.

Area code for Moscow – 495/499

11.7 Credit Cards

Major credit cards are widely accepted at hotels, restaurants, shops, etc. **Visa, MasterCard, American Express,** can be used at establishments, however, some restaurants and small shops accept cash payments only.

11.8 Currency and ATMs

The official currency of the Russian Federation is Ruble (RUR). All payments on the territory of the Russian Federation must be done in Russian RUR. Credit card payments will also be carried out in RUB
Currency exchange points are located at Sheremetyevo, Domodedovo and Vnukovo airports, main hotels and banks. Major currencies accepted for exchange are EUR and USD, some bank accept GBP. Currency exchange rates vary depending on the policies of a bank. Banks usually take commission for money exchange and participants are advised to take it into consideration. When making a currency exchange, banks also require to provide a passport. You may exchange RUB into EUR or USD with no limits at any time at currency exchange points.

It is also possible to use the ATMs located in banks, hotels, large shopping centers.

Relevant information about the currency exchange rate can be found at http://www.cbr.ru/eng/daily.aspx

11.9 Travel Health Insurance

First aid, if necessary, can be provided to the participants free of charge, however, any medical services provided by clinics, hospitals, pharmacies or other health care institutions must be paid for by the participants. The prices for services provided by commercial clinics in Russia are high so in case of treatment in hospitals it would be more convenient to use health insurance policies. The participants are encouraged to clarify the policy provisions with a chosen insurance company.

11.10 Mobile Phones Information

Most modern cell phones can work in several settings that can use roaming services in different networks. Most of the GSM-phones in use in Russia, supporting the protocols of GSM-900 and GSM-1800, or in networks GSM-850 and GSM-1900. Almost all of the UMTS-phones can work in GSM networks.
For roaming the participants need to contact their mobile network operator.

- ### 11.11 Internet

Broadband internet services are available at specified locations of the meeting venue, most hotels and at internet cafés in the city.

13. Workshop security

Access to workshop venue will be granted only to the participants displaying ID badges. All meeting participants are requested to visibly display their meeting ID badges at all times while in all meeting areas.

Annex A: Draft Agenda

	Wednesday, 4 July 2012
10:00-11:00	**Registration and welcome coffee**
11:00-11:30	**Opening Session** **Chairmen (moderators): Khaitov R.M., Kiselev M.Ph.**
	Word of welcome from Ministry of Health of Russia
	Word of welcome from FMBA (Federal Medical-Biological Agency) of Russia
	Word of welcome from by APEC Health Working Group
	Word of welcome from APEC Secretariat
	Word of welcome from the Contractor
	Word of welcome from Project overseer, Academician of RAS and RAMS, Professor R.M.Khaitov
11:30-14:00	**Session I.** **Chairmen (moderators): Khaitov R.M., Kiselev M.Ph.**
	1. Rerks-Ngarm S. (Thailand). The Thai HIV Prime Boost Vaccine Trial (RV144) and subsequent studies: key information from HIV vaccine trial in Thailand (30 min).
	2. Karamov E.V. (Russian Federation). HIV/AIDS in Russia and biomedical prevention (30 min).
	12:30-13:00 Coffee break
	3. Shaari Bin Ngadiman (Malaysia). Responses to HIV and AIDS in Malaysia (30 min).
	4. Gudima G.O. (Russian Federation). HIV/AIDS vaccines in Russia: development and clinical trials (30 min).
14:00-15:00	Lunch break
15:00-16:30	**Session II. The role of HIV vaccines as a part of comprehensive approach to control HIV epidemic in APEC region** **Moderators: Karamov E.V., Jose Luis Sebastian Mesones.**
	Announced presentation • Sidorovich I.G., Nikolaeva I.A. (Russian Federation). Rationale for HIV vaccine design (30 min). • Doan Thi Thuy (Vietnam). HIV in Vietnam and hope of an effective vaccine for prevention (30 min).
	Discussion **Participants**: Jose Luis Sebastian Mesones (Peru), Mangalam Sinniah (Malaysia), Shaari Bin Ngadiman (Malaysia), Rossana A. Ditangco (Phlippines), Jose Gerard B. Belimac (Philippines), Heinner Guio Chunga (Peru), Supachai Rerks-Ngarm

	(Thailand), Namwat Chawetsan (Thailand), Luxi Riajuni Pasaribu (Indonesia), Phan Thi Thu Huong (Vietnam), Viviana Garcia (Chile), Gudima G.O. (Russian Federation), Karamov E.V. (Russian Federation)
	Thursday, 5 July 2012
11:00-12:30	**Session III. Clinical trials. The existing experience in HIV vaccine related issues**. **Moderators: Rerks-Ngarm S., Gudima G.O.**
	Announced presentations: • Ditangco Rossana A. (Philippines). The potential of a low HIV prevalence country to participate in HIV vaccine clinical trial (30 min). • Pasaribu Luxi Riajuni (Indonesia). Situation with AIDS control in Indonesia (30 min).
	Discussion **Participants:** Heinner Guio Chunga (Peru), Rerks-Ngarm S. (Thailand), Mangalam Sinniah (Malaysia), Shaari Bin Ngadiman (Malaysia), Jose Gerard B. Belimac (Philippines) Namwat Chawetsan (Thailand), Phan Thi Thu Huong (Vietnam), Doan Thi Thuy (Vietnam), Viviana Garcia (Chile), Jose Luis Sebastian Mesones (Peru), Gudima G.O. (Russian Federation), Karamov E.V. (Russian Federation), Nikolaeva I.A. (Russian Federation), Sidorovich I.G. (Russian Federation)
12:30-13:00	**Coffee break**
13:00-14:00	**Session IV. Normative/Legislative/Ethical issues** **Moderators: Nikolaeva I.A., Phan Thi Thu Huong.**
	Discussion **Participants:** Viviana Garcia (Chile), Phan Thi Thu Huong (Vietnam), Mangalam Sinniah (Malaysia), Shaari Bin Ngadiman (Malaysia), Rerks-Ngarm S. (Thailand), Jose Gerard B. Belimac (Philippines), Rossana A. Ditangco (Phlippines), Namwat Chawetsan (Thailand), Doan Thi Thuy (Vietnam), Jose Luis Sebastian Mesones (Peru), Heinner Guio Chunga (Peru), Luxi Riajuni Pasaribu (Indonesia), Gudima G.O. (Russian Federation), Karamov E.V. (Russian Federation), Nikolaeva I.A. (Russian Federation), Sidorovich I.G. (Russian Federation)
14:00-14:30	**Coffee-break**
14:30-15:30	**Session V. Discussion and Acceptance of the Project of the Final Document** **Moderators: Khaitov R.M., Kiselev M.Ph.**
	1. Discussion on the Project of the Workshop Final Document 2. Acceptance (Approval) of the Project of the Workshop Final Document 3. Workshop closing.
15:30-17:30	**Closing dinner**

PRELIMINARY LIST OF WORKSHOP PARTICIPANTS

#	name	Country, position
1	Doan Thi Thuy	(Vietnam, Vice Director, Company for Vaccine and Biological Production No.1)

2	Phan Thi Thu Huong	(Vietnam, Deputy General Director, Vietnam Authority of HIV/AIDS Control, Ministry of Health),
3	Heinner Guio Chunga	(Peru, Chief of Laboratory Molecular Biology and Immunology, National Institute of Health-Peru),
4	Jose Luis Sebastian Mesones	(Peru, National coordinator, National AIDS Control Program - Ministry of Health).
5	Mangalam Sinniah	(Malaysia, Consultant, Clinical Microbiologist/Virologist, Ministry of Health).
6	Shaari Bin Ngadiman	(Malaysia, Ministry of Health, Deputy Director of Disease Control & Head of AIDS section)
7	Rossana A. Ditangco	(Phlippines, Medical Specialist III, Research Institute for Tropical Medicine),
8	Jose Gerard B. Belimac	(Philippines, Program Manager, National AIDS and STI Prevention and Control Program, Infectious Disease Office),
9	Supachai Rerks-Ngarm	(Thailand, Medical Physician, Advisory Level, Department of Disease Control, Ministry of Public Health)
10	Namwat Chawetsan	(Thailand, Director, Bureau of Tuberculosis, Department of Disease Control, Ministry of Public Health),
11	Luxi Riajuni Pasaribu	(Indonesia, Researcher, National Board of Research and Development, Ministry of Health),
12	Viviana Garcia	(Chile, Technical Advisor in Pharmaceutical Policies, Ministry of Health),
13	Gudima G.O.	(Russian Federation, Head of Laboratory, Institute of Immunology,),
14	Karamov E.V.	(Russian Federation, Head of Laboratory, Institute of Virology)
15	Nikolaeva I.A.	(Russian Federation, Senior Researcher, Department of AIDS Immunobiology, Institute of Immunology),
16	Sidorovich I.G	(Russian Federation, Head of Department of AIDS Immunobiology, Institute of Immunology)

Annex B

APEC Workshop
"HIV vaccines as a part of complex approach to AIDS prevention and control in APEC region",
Moscow, Russian Federation
4-5 July, 2012

Registration Form

1. General profile

Name: .....
Sex: Male ( ) Female ( )
Name and Designation (to appear in the name badge): .....
Organization: ..... Position: .....
Country.....
Contact address: .....
Telephone number: ..... Fax number: .....
Email address: .....

Passport Number:.....
Date of issue: .....
Date of expiry: .....
Place of issue: .....

Date of birth: ....
Nationality/Country/Economy: .....

2. Experience in

Please kindly provide us one short paragraph (150 words) on your expertise and experience In the workshop themes, such as

1. (1) The role of HIV vaccines as a part of comprehensive approach to control HIV epidemic in APEC region;
2. (2) Clinical trials. The existing experience in HIV vaccine related issues;
3. (3) Normative/Legislative/Ethical issues.

Also please select your preference for participation in the workshop sessions (see Agenda).

3. Submission of the Registration Form

Please fill in all fields of the Registration Form (one form for one participant) and send it to the workshop organizing committee at: goudima@gmail.com and copy nikolaeva.immune@mail.ru at your earliest convenience **before 23 June, 2012.**

Annex C. Visa requirements to enter Russia for APEC economies' passport holders

Economy	Diplomatic Passport	Official Passport	Ordinary Passport
Australia	Required	Required	Required
Brunei Darussalam	Not required (unless for a stay of more than 14 days)	Not required (unless for a stay of more than 14 days)	Required
Canada	Required	Required	Required
Chile	Not required (unless for a stay of more than 3 months)	Not required (unless for a stay of more than 3 months)	Not required (unless for a stay of more than 90 days)
China	Not required (unless for a stay of more than 30 days)	Required	Required
Hong Kong, China	Not required (unless for a stay of more than 14 days)	Not required (unless for a stay of more than 14 days)	Not required (unless for a stay of more than 14 days)
Indonesia	Not required (unless for a stay of more than 14 days)	Not required (unless for a stay of more than 14 days)	Required
Japan	Required	Required	Required
Korea	Not required (unless for a stay of more than 90 days)	Not required (unless for a stay of more than 90 days)	Required
Malaysia	Required	Required	Required
Mexico	Not required (unless for a stay of more than 90 days)	Not required (unless for a stay of more than 90 days)	Required
New Zealand	Required	Required	Required
Papua New Guinea	Required	Required	Required
Peru	Not required	Not required	Not required (unless for a stay of more than 90 days)
Philippines	Not required (unless for a stay of more than 90 days)	Not required (unless for a stay of more than 90 days)	Required
Singapore	Required	Required	Required
Chinese Taipei			Required
Thailand	Not required (unless for a stay of more than 90 days)	Not required (unless for a stay of more than 90 days)	Not required (unless for a stay of more than 30 days)
United States	Required	Required	Required
Viet Nam	Not required (unless for a stay of more than 90 days)	Not required (unless for a stay of more than 90 days)	Required

e) Workshop agenda:

Agenda of the Workshop
4-5 July 2012, Moscow, Russian Federation

	Wednesday, 4 July 2012
10:00-11:00	**Registration and welcome coffee**
11:00-11:30	**Opening Session** **Chairmen (moderators): Khaitov R.M., Kiselev M.Ph.**
	Word of welcome from Ministry of Health of Russia
	Word of welcome from by APEC Health Working Group (Svetlana Axelrod)
	Word of welcome from Federal Medical-Biological Agency of Russia (M.Ph. Kiselev)
	Word of welcome from APEC community (Supachai Rerks-Ngarm)
	Word of welcome from the Contractor (Natalia Makarycheva)
	Word of welcome from Project Overseer, Academician of RAS and RAMS, Professor R.M.Khaitov
11:30-14:00	**Session I.** **Chairmen (moderators): Khaitov R.M., Kiselev M.Ph.**
	1. Rerks-Ngarm S. (Thailand). The Thai HIV Prime Boost Vaccine Trial (RV144) and subsequent studies: key information from HIV vaccine trial in Thailand (30 min).
	2. Karamov E.V. (Russian Federation). HIV/AIDS in Russia and biomedical prevention (30 min).
	12:30-13:00 Coffee break
	3. Shaari Bin Ngadiman (Malaysia). Responses to HIV and AIDS in Malaysia (30 min).
	4. Gudima G.O. (Russian Federation). HIV/AIDS vaccines in Russia: development and clinical trials (30 min).
14:00-15:00	Lunch break
15:00-16:30	**Session II. The role of HIV vaccines as a part of comprehensive approach to control HIV epidemic in APEC region** **Moderators: Gudima G.O., Jose Gerard B. Belimac.**
	Announced presentation • Nikolaeva I.A., Sidorovich I.G. (Russian Federation). Rationale for HIV vaccine design (30 min).

	• Doan Thi Thuy (Vietnam). HIV in Vietnam and hope of an effective vaccine for prevention (30 min).
	Discussion **Participants**: Mangalam Sinniah (Malaysia), Shaari Bin Ngadiman (Malaysia), Rossana A. Ditangco (Phlippines), Jose Gerard B. Belimac (Philippines), Heinner Guio Chunga (Peru), Supachai Rerks-Ngarm (Thailand), Namwat Chawetsan (Thailand), Luxi Riajuni Pasaribu (Indonesia), Phan Thi Thu Huong (Viet Nam), Gudima G.O. (Russian Federation), Karamov E.V. (Russian Federation), Nikolaeva I.A. (Russian Federation),
	Thursday, 5 July 2012
11:00-12:30	**Session III. Clinical trials. The existing experience in HIV vaccine related issues**. **Moderators: Rerks-Ngarm S., Karamov E.V.**
	Announced presentations: • Ditangco Rossana A. (Philippines). The potential of a low HIV prevalence country to participate in HIV vaccine clinical trial (30 min). • Pasaribu Luxi Riajuni (Indonesia). Situation with AIDS control in Indonesia (30 min).
	Discussion **Participants:** Heinner Guio Chunga (Peru), Rerks-Ngarm S. (Thailand), Mangalam Sinniah (Malaysia), Shaari Bin Ngadiman (Malaysia), Jose Gerard B. Belimac (Philippines) Namwat Chawetsan (Thailand), Phan Thi Thu Huong (Viet Nam), Doan Thi Thuy (Vietnam), Gudima G.O. (Russian Federation), Karamov E.V. (Russian Federation), Nikolaeva I.A. (Russian Federation), Sidorovich I.G. (Russian Federation)
12:30-13:00	**Coffee break**
13:00-14:00	**Session IV. Normative/Legislative/Ethical issues** **Moderators: Nikolaeva I.A., Phan Thi Thu Huong.**
	Announced presentation: • Korobova S. (Russian Federation). Acceptance of HIV/AIDS vaccine in Russia (30 min).
	Discussion **Participants:** Phan Thi Thu Huong (Vietnam), Mangalam Sinniah (Malaysia), Shaari Bin Ngadiman (Malaysia), Rerks-Ngarm S. (Thailand), Jose Gerard B. Belimac (Philippines), Rossana A. Ditangco (Phlippines), Namwat Chawetsan (Thailand), Doan Thi Thuy (Viet Nam), Heinner Guio Chunga (Peru), Luxi Riajuni Pasaribu (Indonesia), Gudima G.O. (Russian Federation), Karamov E.V. (Russian Federation), Nikolaeva I.A. (Russian Federation), Sidorovich I.G. (Russian Federation)
14:00-14:30	**Coffee-break**
14:30-15:30	**Session V. Discussion and Acceptance of the Project of the Final Document** **Moderators: Sidorovich I.G., Heinner Guio Chunga.**
	4. Discussion on the Draft of the Workshop Final Document 5. Acceptance (Approval) of the Draft of the Workshop Final Document 6. Workshop closing.
15:30-17:30	**Closing dinner**

f) List of participants of the Workshop

	Name	Country and Duty
1.	**Doan Thi Thuy**	**Viet Nam**, Deputy Director of the Company for Vaccine and Biological Production No.1
2.	**Heinner Guio MD, PhD**	**Peru,** Chief of Molecular Biology and Immunology Laboratory, National Institute of Health
3.	**Jose Gerard B. Belimac, MD, MPH**	**Phlippines**, Program Manage, National Center For Disease Prevention and Control, Department of Health
4.	**Luxi Riajuni Pasaribu, S.Si, M.Sc.PH**	**Indonesia,** Researcher, National Board of Research and Development, Ministry of Health
5.	**Dr. Mangalam Sinniah**	**Malaysia,** Consultant Clinical Microbiologist/Virologist, Ministry of Health
6.	**Dr. Chawetsan Namwat**	**Thailand,** Director, Bureau of Tuberculosis
7.	**Dr. Phan Thi Thu Huong**	**Viet Nam,** Deputy General Director, Vietnam Authority of HIV/AIDS Control
8.	**Dr. Rossana Ditangco**	**Phlippines,** Medical Specialist, Research Institute for Tropical Medicine
9.	**Shaari Bin Ngadiman**	**Malaysia,** Deputy Director of Disease Control & Head of AIDS Section, Ministry of Health
10.	**Dr. Supachai Rerk-Ngarm**	**Thailand,** Medical Physician, Department of Disease Control, Ministry of Public Health of Thailand
11.	**Olga Averina**	**Russia**, Epidemiologist, Head of the Center of Hygiene and Immunology
12.	**Svetlana Axelrod**	**Russia**, Deputy Head of the Department of International Cooperation on Health, Ministry of Health. **Chair of APEC Health Working Group**
13.	**Lenard Axenov**	**Russia**, Head of an epidemiology department, Head center of hygiene and immunology of Russia
14.	**Vyacheslav Bayramov**	**Russia**, Head of department live systems, Ministry of Education & Science of Russia
15.	**Ksenia Beresneva**	**Russia,** Expert of International division, Federal Medical Biological Agency of Russia (FMBA)
16.	**Sergey Bogdan**	**Russia**, Head doctor, Head center of hygiene and immunology, FMBA
17.	**Valery Varenik**	**Russia**, Head of the Department of science researches arrangement, FMBA
18.	**Elena Vasilieva**	**Russia**, Consultant on management, Department of science researches arrangement, FMBA
19.	**Valery Vedishchev**	**Russia**, Epidemiologist, Head center of hygiene and immunology, FMBA
20.	**Nadezhda Gorodilova**	**Russia**, Acting head of virological laboratory, Head center of hygiene and immunology, FMBA
21.	**Georgy Gudima**	**Russia**, Head of laboratory , Institute of immunology, FMBA
22.	**Edward Karamov**	**Russia**, Head of laboratory, Scientific Research Institute of Virusology, Ministry of Health
23.	**Michail Kiselev**	**Russia**, Deputy Head, Federal Medical Biological Agency
24.	**Svetlana Korobova**	**Russia**, Leading researcher, Institute of immunology, FMBA
25.	**Alexey Mazus**	**Russia**, Director, Moscow AIDS municipal center

26.	**Irina Nikolaeva**	**Russia**, Leading researcher, Institute of immunology, FMBA
27.	**Alexander Olshansky**	**Russia,** Head, Moscow AIDS municipal center
28.	**Igor Sidorivich**	**Russia**, Head of division, Institute of immunology, FMBA
29.	**Rakhim Khaitov**	**Russia,** Director, Institute of immunology, FMBA; **Project Overseer**
30.	**Elena Tsiganova**	**Russia**, Head of the Moscow municipal center AIDS
31.	**Natalia Makarycheva**	**Russia**, Director, Department of international projects, Borlas Security Systems (BSS)
32.	**Yuriy Kalik**	**Russia,** Director of International Projects, Department of international projects, BSS
33.	**Vladlen Grigoriev**	**Russia**, Director, Marketing Department, BSS
34.	**Zinaida Sopina**	**Russia,** Manager, Marketing Department, BSS
35.	**Vladimir Berestok**	**Russia**, Researcher, Institute of immunology, FMBA
36.	**Olga Khailovskaya**	**Russia**, 3rd secretary, FPEC Department, Ministry of Foreign Affairs of Russia
37.	**Vagif Gasanov**	**Russia**, Researcher, Institute of immunology, FMBA
38.	**Alexander Shevalier**	**Russia,** Deputy Head of Laboratory Institute of Virusology, Ministry of Health
39.	**Dmitriy Mazurov**	**Russia,** Institute of Immunology, FMBA
40.	**Leonid Skliarov**	**Russia,** Institute of Immunology, FMBA
41.	**Natalia Andronova**	**Russia,** Institute of Immunology, FMBA
42.	**Maria Krucko**	**Russia,** Marketing Department, BSS

As seen from the list of participants 42 persons took part in the Workshop. Speakers presented 9 reports and lectures. All participants actively participated in discussions, exchange of views and opinions.

g) The Workshop Pictures


HIV vaccines as a part of complex
approach to AIDS prevention and control
in APEC region


PHILIPPINES
Luzon
Metro Manila
Visayas
Mindanao

h) Final Document of the Workshop

APEC Workshop
"HIV vaccines as a part of complex approach to AIDS prevention and control in APEC region"
(July 4-5, 2012, Moscow, Russia)

Final document

HIV pandemic represents the global threat to human health and security, demographic situation, human resources development, for sustainable development of the region, and world and APEC economy. Fighting with pandemic requires the development of the comprehensive international intergovernmental approach. This approach includes socio-behavioral intervention, bio-medical preventive measures, diagnostics, treatment and care. The introduction of potent antiviral drugs has lessened the impact of AIDS in developed countries, but their use in developing countries is unlikely to slow HIV epidemic. Besides, these drugs have adverse side effects, cannot clear virus from the body and require lifelong use. Effective HIV vaccine would offer the best hope and important complementary tool empowering body system of those who fall into the situation of no choice of protective measures, and subsequently for the future control of HIV pandemic.

Therefore HIV vaccine is an urgent need for APEC economies.

The present Workshop became a platform for sharing lessons and experience in the field of HIV vaccine development.

The aim of this Workshop, organized during the Russia chairmanship in APEC, is to help APEC economies to enhance information and experience sharing in the field of HIV vaccines development and implementation as a part of anti AIDS comprehensive approach in order to formulate more effective AIDS prevention strategies in the region.

Three main fields were discussed at the Workshop expert sessions:

(1) The role of HIV vaccines as a part of comprehensive approach to control HIV epidemic in APEC region;

(2) Clinical trials. The existing experience in HIV vaccine related issues;

(3) Normative/Legislative/Ethical issues.

Fruitful discussion allowed participants to make conclusion in the following:

HIV infection / AIDS is the life-threatening disease and very important concern of public health in APEC economies, which needs governmental support. It is necessary to improve the strategies of counteraction to this infection. HIV vaccine is the one of the most perspective tools for the control of HIV infection, and it is rationale to expand works on the development of HIV vaccine.

There are different levels of investigations in the field of development of HIV vaccine, capacity building, preparedness for clinical trials and further implementation in APEC economies. It seems rationale to improve sharing of information, research achievements, clinical trials experience. Establishment of international collaboration network in these fields is one of the key factors to support progress in HIV/AIDS counteraction.

Clinical trials are the essential part in HIV vaccine development. Collaboration and coordination between APEC economies are very important to perform international multicentral clinical trials of effectiveness of new candidate HIV vaccines, which in future may be approved for implementation in APEC region. Collaboration in harmonization of normative, legislative and ethical aspects of clinical trials will be strategic mechanism to facilitate the discovery of HIV vaccine for APEC community and ultimately, the global community.

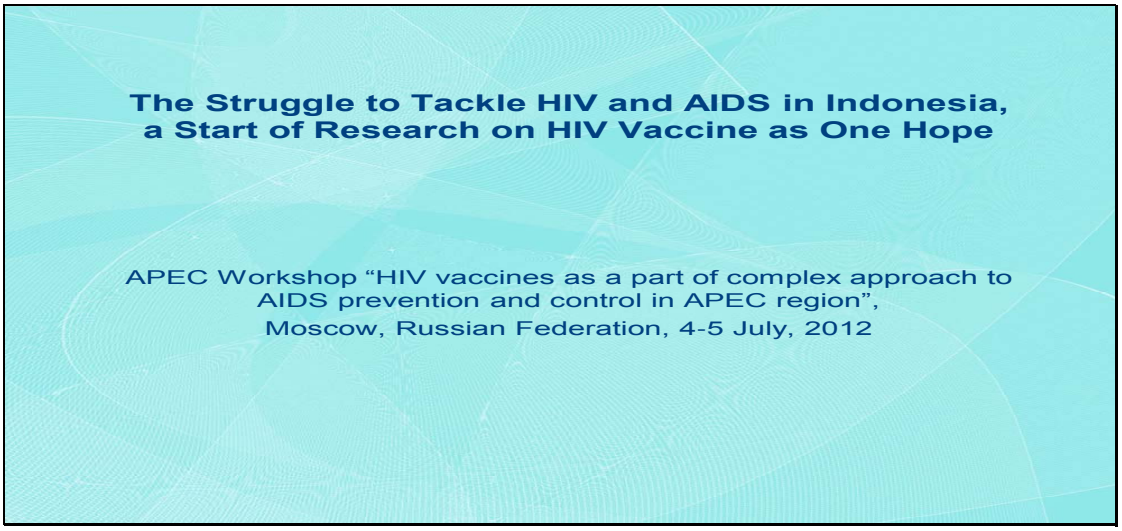
The effect of HIV vaccine is being determined not only by the effectiveness of vaccine itself, but strongly depends on the acceptance of vaccine in population. It is reasonable to support efforts in distribution of information about HIV vaccine safety, properties,

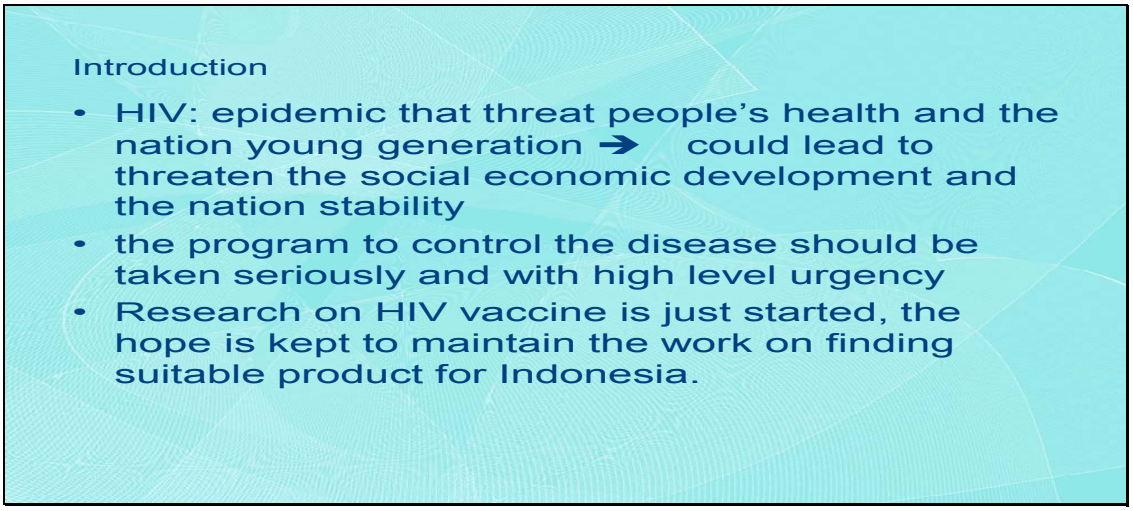
investigations in the field of HIV vaccines and other efforts improving the acceptance of HIV vaccines.

Workshop was very useful, all set tasks were fulfilled. Workshop made a good contribution to the member economies in organizing cooperation and in creation of expert network in order to provide sustained sharing of expertize in the field of AIDS prevention, including HIV vaccine development and clinical trials. This, in turn, will promote HIV vaccine implementation and contribute to APEC Human Resources Development Action Plan and ultimately, will promote to halt and reverse the spread of HIV and contribute to the achievement of the Millennium Development goals.

The above "Final document" was distributed among the participants during the Workshop. It was considered at the end of the Workshop and after including of all notes and remarks preliminary adopted. Afterwards it was disseminated through APEC Secretariat and received approval of all Workshop participants.

i) Annex 1


The Struggle to Tackle HIV and AIDS in Indonesia, a Start of Research on HIV Vaccine as One Hope
APEC Workshop "HIV vaccines as a part of complex approach to AIDS prevention and control in APEC region",
Moscow, Russian Federation, 4-5 July, 2012


Introduction
• HIV: epidemic that threat people's health and the nation young generation ➔ could lead to threaten the social economic development and the nation stability
• the program to control the disease should be taken seriously and with high level urgency
• Research on HIV vaccine is just started, the hope is kept to maintain the work on finding suitable product for Indonesia.

HIV and AIDS epidemic and responses situation

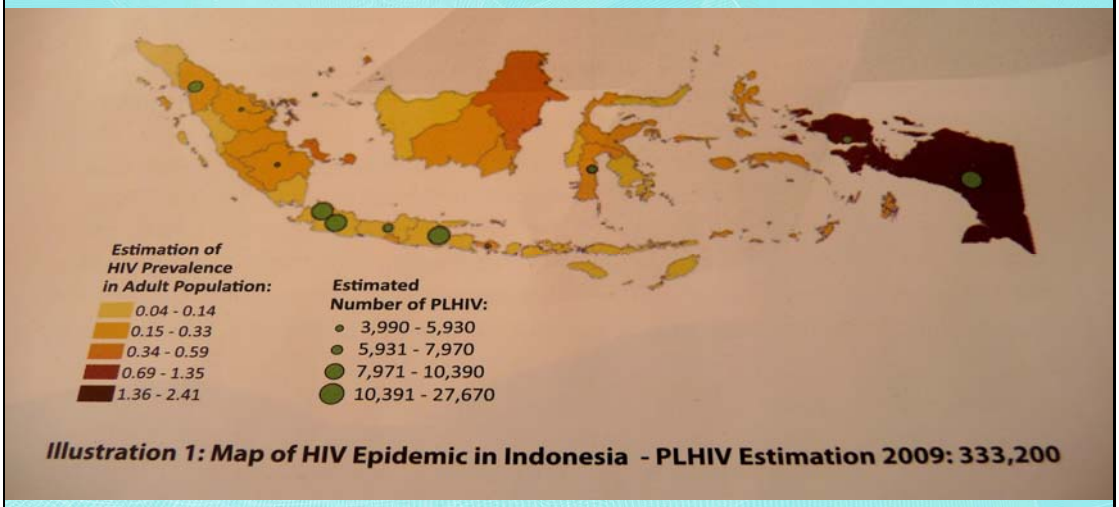


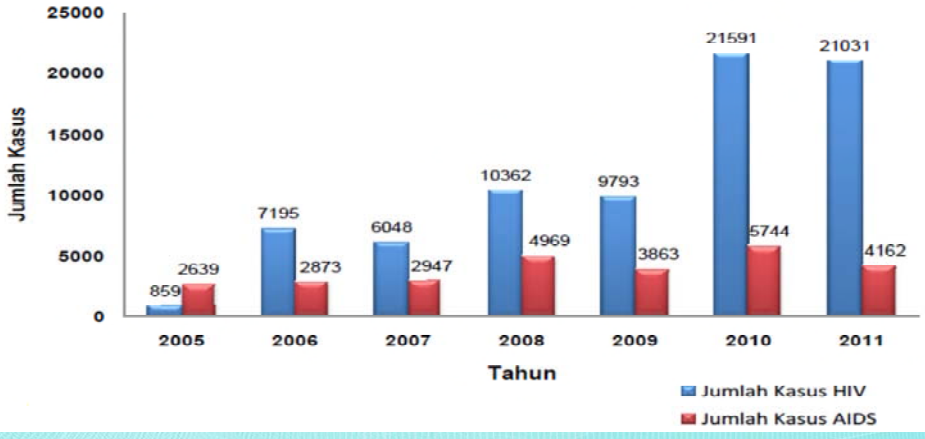
Illustration 1: Map of HIV Epidemic in Indonesia - **PLHIV Estimation 2009: 333,200**

Indonesia's HIV-AIDS situation

- Indonesia MDGs: control the HIV and AIDS transmission and to start the reduction of new cases in 2015, also to provide Universal Access to treatment for all those who need it.
- There is a significant increasing number and area of HIV and AIDS infection:
  - In 2006: 16 provinces reporting cases
  - In 2007: 32 provinces reporting cases
  - In 2004: number of cases is 2,682
  - In September 2007 (10,384 cases) ~ 4 times
  - The HIV cases cumulatively from 1987-2011 are 76,879 and the AIDS cases are 29,879

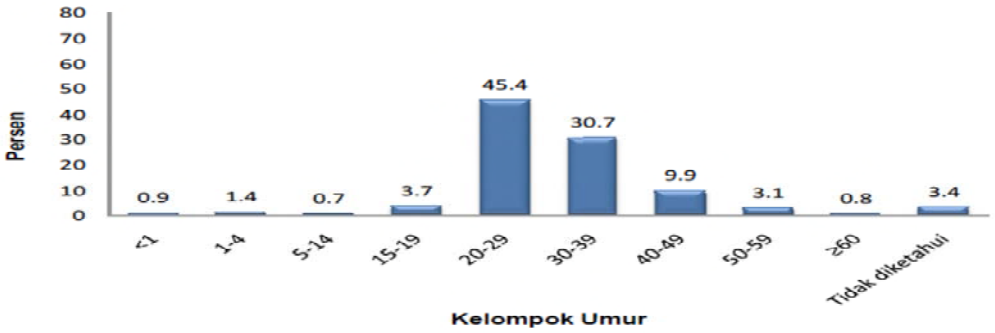
Number of cases of HIV and AIDS in Indonesia 2005-2011

Grafik 1. Jumlah Kasus HIV-AIDS Menurut Tahun di Indonesia, 2005-2011



Cumulative AIDS cases according to age group from 1987-2011

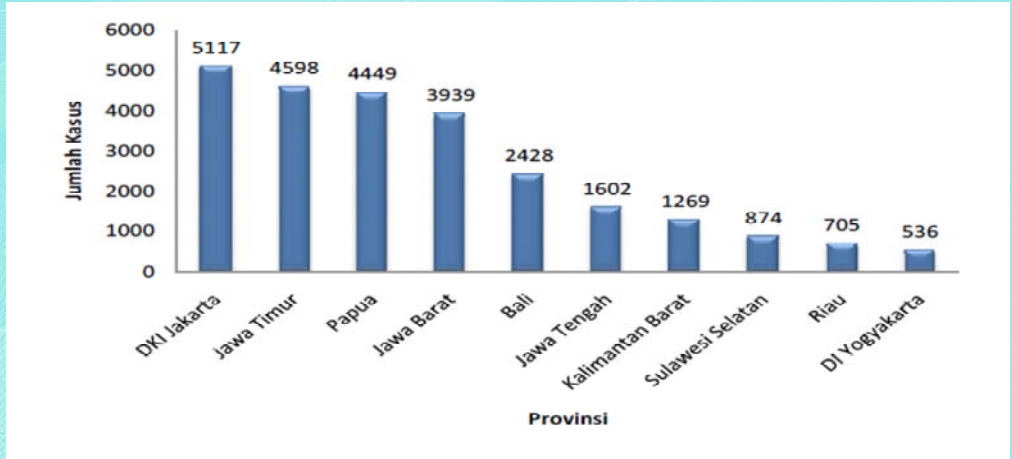
Grafik 2. Persentase Kumulatif Kasus AIDS Menurut Kelompok Umur di Indonesia Tahun 1987-2011



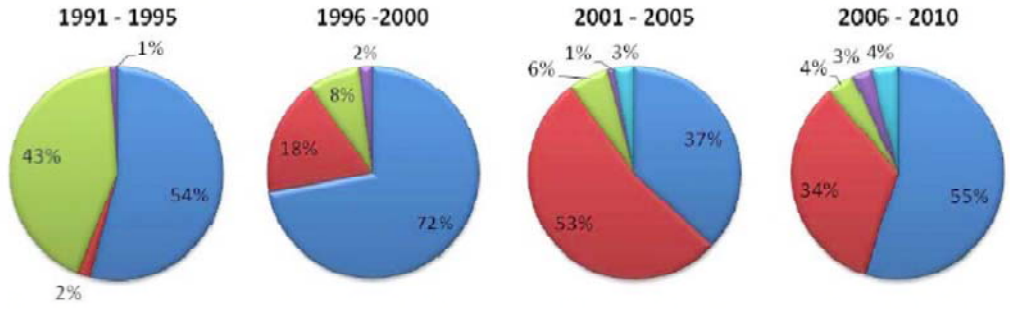
- About 85% of the cases are in 15 – 49 years old group

- Prevalence of 15-49 group increase from 0.22% to 0.37% by 2014 by mathematical modeling and trend analysis
- Biggest proportion according to sex cumulatively is man (70.8%), but in 2011 woman infected is increasing to 44.1%
- Data 1987-2011 the housewife has the second largest cases after self-employed worker.
- Women and children position in culture still low ➔ under reported cases
- Distribution of cases are vary according to provinces (est. prevalence on adult in 2008 is 0.22%), but in Papua and West Papua have shifted to a generalized epidemic with 2,4% among 15-49 years old population.

Cumulative highest AIDS cases 1987-2011 according to provinces



Cumulative percentage of AIDS cases due to risk per 5 years period



- Heterosexual IDU MSM Others Unknown

Biggest risk group: heterosexual and IDU

ART's role

- Decreasing the mortality from AIDS ➔ from 46% in 2006 to 17% in 2008
- Increasing % of ART coverage ➔ from 2006 (24.8%) compared to 2009 (38.4%).
- The facilities keep extended ➔ 180 facilities available in 2009, it become 235 facilities in 2011
- Greater need if the CD4 criteria for prescription on ART rises, eg. a CD4 count of 200 to 350. Also, if the prevention program not run effectively, it is expected the need of ARV will increase three fold from 30,100 in 2008 to 86,800 in 2014 among the 15-49 years old group.
- Indonesia need effective and economics advantageous strategies.

Targets of the Action Plan:

- Comprehensive and effective prevention programs ➔ 80% of key population.
- Behavioral change by use of a) consistent and correct condom in 60% of high risk sexual transactions and b) sterile injection equipment to 60% of IDU.
- All eligible PLHIV receive ARV in supporting environment and provision of effective referrals.
- HIV(+) pregnant women and their children will receive ARV prophylaxis as appropriate.
- Infected and affected person (esp. orphans and widows) ➔ access to and utilize social and economic support as needed.
- Civil society meaningful role in eradicate stigma and discrimination towards PLHIV and their family.
- All level government commitment in budget allocations

Biomedical and Biotechnology Research on HIV and AIDS

- Research institutions carry out biomedical and biotechnology reseach ➔ seed vaccine and herbal medicines.
- Preventive HIV vaccine ➔ potential strategies
- Curative HIV vaccine ➔ alternative solution to reduce the economics burden in providing ARV treatment
- Indonesia has started investigation on HIV vaccine using Indonesian seed vaccine.
- The funding: Indonesia government (research funding), national company, and International agency. Minimum needed is Rp 200,000,000,000 or US$ 21,052,631.58 (current rate).
- University of Indonesia lab.: initial vaccine research in 2011 ➔ end in 2012, also others
- Protein virus obtained: Gag, Pol, Envelop, and Protein Accessories (Tat, Rev).
- Vaccine platforms developed: DNA, subunit recombinant protein, and VLP (Baculovirus)

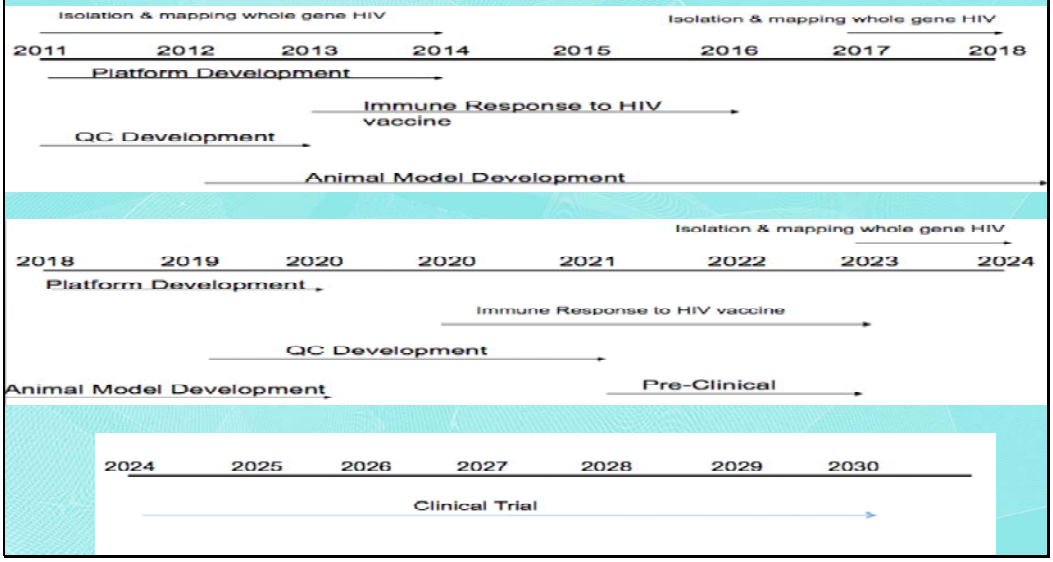
No	Research	Institution	Technology	Funding	Result
1	Pathogenesis of viral infection	University of Indonesia	Viral culture, Serology and Immunoassay; ELISA, Western Blot, ELISPOT		Immune response of HIV patients, HIV sequence data
2	Development of: vaccine, herbal medicine, diagnostic	University of Indonesia	Molecular characterization, recombinant DNA, protein engineering	Pharmaceutical National Company (Biofarma): Rp 2,000,000,000 (US$ 210,526.3) for the vaccine	HIV drug resistance, diagnostic system, recombinant protein3
3	Genotyping of HIV-1 from HIV patients	National Institute of Health Research and Development	Sequencing	Gov. Research funding (MOH) The research have been taken in 3 years (2008, 2010, 2011) and each years has used: Rp 700,000,000 (US$ 73,685 in today's rate); Rp 700,000,000 (US$ 73,685 in today's rate); and Rp 1,500,000,000 (US$157,895 in today's rate)	Jakarta: subtype E, AE, and B East Java: subtype AE, E, and B West Kalimantan: subtype AE, E, A, C, AC Papua: subtype AE, and C Riau Islands: subtype AE, AG, and A Maluku: subtype AE and B South Sulawesi: subtype AE and B North Sumatera: subtype AE, AG, and B West Sumatera: subtype AE and B North Sulawesi: subtype AE, B, and D

4	Development of herbal medicine and drug resistance from previous study specimens	National Institute of Health Research and Development	Study the derivat of Cathecin Uncaria and whole genome analysis	Gov. Research funding (MOH) For the herbal medicine: Rp 758,101,000 (US$ 79,800). For drug resistance: Rp 1,713,700,000 (US$ 180.390)	In going in 2012
5	1. Molecular database from local isolate from prisoners in Central Java 2. Host exploration for therapy or expression system 3. Molecular database from MSM, transgender, sex worker in Central Java 4. HIV patient monitorin in Dr Moewardi Hospital Surakarta Central Java 5. VLP construction for vaccine candidate or epitop vaccine carier	University of 11 March (Surakarta, Central Java		For all about Rp 3,000,000,000 (US$ 315,789.474) From Gov Research Funding (Dikti) 50%, International Agency, and Ministry of Health	• Central Java prisoners: HIV: CRF01_AE (varian of CRF01_AE?) • Biodiversity data with therapy or expression system potency • Central Java MSM, transgender, sex worker: HIV: CRF01_AE (varian of CRF01_AE?) • Molecular epidemiologi data; Co-infection (serologic & moleculer) HBV, HCV, HDV, HTLV-1/2, TTV, M. tb, NTM, Toxoplasma. Candida sp. Aspergillus sp; imunology profil of HIV patient; polimorfisme data; Plasmid and whole genome; cared community • VLP HBc, VLP HbsAg: in process VLP HCV, VLP HIV, VLP Influenza A, VLP HMPV, VLP TTV

Laboratory capability on HIV Vaccine Research

Facility	University of Indonesia	National Institute of Health Research and Development	Biofarma
Lab. DNA recombinant	v		v
Serology Facility	v	v	
Confocal mikroscope	v		
Electron microscope			v
Sequencing	v	v	v
Flowcytometer	v	v	v
ELISPOT reader	v		v
Chromatografi (HPLC)		v	v
Animal Lab. for Transgenic Animal			
Lab. for HIV culture	v		
BSL - 3	v	v	

Roadmap on HIV Vaccine Research



The Phase

Activity	Years Period		
Isolation and mapping whole genome HIV	2011-2014	2017-2018	2023-2005
Vaccine Platform development	2011-2014	2018-2020	
Immunoassay development for Immune response analysis	2011-2013	2019-2021	
• Immune response analysis • AB neutralization response • Cyto-toxic cell-T response • Cell T CD4 response • Immune immunity response			
Immune Response toward HIV vaccine	2012-2016	2021-2023	
Animal model development: 1. Transgenic mice 2. Primate (will work with Primate Center Study in University of Bogor Agriculture)	2012-2020		
Preclinical Trial and clinical trial	2021-2023		

Challenges

- The human resources available ➔ needs more coordination and interactions ➔ to enhance the speed as the need of Indonesia vaccine is ↗ (to reduce funding for more ARV needed as now is free for all)
- Limited funding and long period of time needed
- Transgenic mice facility has not been resolved.
- Issue on Intellectual Property Right.
- The community response toward HIV vaccine has not known. Subordinate public health research need to be done in the same time.
- No experience on doing HIV vaccine clinical trial.

Conclusion

- Indonesia needs to be prepared with the potential increasing number of HIV and AIDS patients which are valuable
- Program and Action Plan need to be done with high concern from all parts
- Research institutions have started the work on producing HIV vaccine
- Hopefully, we gain more good results in the research we plan to do in the future and the challenges can be tackled together so the roadmap can be accomplished sooner
- Collaboration within Indonesia and with Asia and International agency is taken as great advantages, thus APEC meeting on this hopefully can lighten the path for it.

T H A N K Y O U

j) Annex2

HIV/AIDS vaccines in Russia: Development and trials

G.O.Gudima
National Research Center Institute of Immunology
Federal Medical & Biological Agency
Russian Federation

Natural HIV-specific immune response is inadequate – it does not remove virus from infected human and does not provide protection against HIV infection *(Nabel G.J., Fauci A.S. Nat. Med., 2010, v.16, p.1389-1391)*.

So the goal of researchers is "to improve" HIV-specific immune response with vaccine.

HIV/AIDS vaccine: properties and tasks

Immune response:
- Cross-reactive neutralizing antibody
- Broadly reactive CD4+-T-cells
- Cross-reactive CD8+-CTL
- Mucosal immunity
- Long term immune memory
- Blockage (or removal) of CC-chemokine receptors

Targets of immune response:
- Envelope proteins: gp120, gp41
- Structure proteins: Gag, Pol
- Regulatory proteins: Tat, Rev, Nef
- Accessory proteins: Vpr

Subtypes
- A, B, C, D, E, F, G, H, J, K

Others properties:
- Безопасность
- Дешевизна и простота производства
- Стабильность
- Удобство применения

Combination of different candidate vaccines and different immunization strategies

Proteins | Peptides | Virus-like particles | Viral and bacterial vectors | DNA vaccines | Adjuvants

1. Decrease of viral transmission
2. Viral replication control
3. Sterilizing immunity

Types of HIV/AIDS vaccines

- **Subunit vaccines (based on HIV recombinant proteins and glycoproteins)**
- **DNA vaccines**
- **Vector based vaccines used viral, bacterial or virus-like particles**
- **Conjugated polymer-subunit vaccines**

All types of HIV/AIDS vaccine are in development in Russia. Russian State Research program “Vaccines of new generation and medical diagnostic system of the future” (1997) was the first coordinated plan for HIV vaccine development in the world.

Conjugated polymer-subunit vaccines – **original vaccines of new generation, which consist of antigen chemically linked (conjugated) with carrier-immunostimulator.**

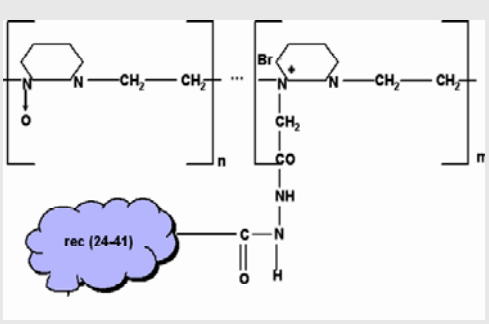
Such vaccine constructions can increase immune response against weak antigens and allow to use lower quantities of antigen. It can be use to elicit antibodies against neutralizing HIV antigens and so make opportunity to convert HIV-specific immune response to protective.

VICHREPOL

Chimeric recombinant protein rec(24-41)

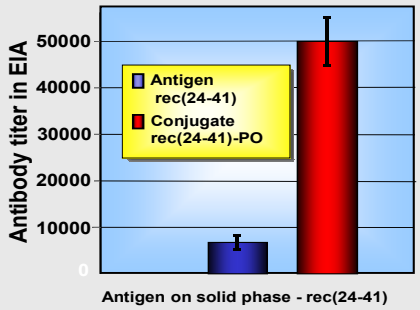
Immunomodulator (Polyoxydonium)

Chemical structure of VICHREPOL



Immune response induced by chimeric recombinant protein rec(24-41) and its conjugate with polyoxydonium (preclinical study)

Immunization of mice with rec(24-41) and its conjugate with polyoxidonium ((10 mcg/mouse, secondary immune response)



VICHREPOL induced HIV neutralizing antibodies

Neutralization index – over 65%

VICHREPOL-induced cell proliferation

	Spontaneous proliferation	LBTR with rec(24-41)	Proliferation index
Spleen	**1000±50 (cpm/10^6 cells)**	10000±300 (cpm/10^6 cells)	**10.0**
Lymph nodes	**600±100 (cpm/10^6 cells)**	5000±100 (cpm/10^6 cells)	**8.3**

Trials of VICHREPOL started the establishment of HIV/AIDS vaccines clinical trials infrastructure (capacity building) in Russia:

- Standardization of methods of testing for different types of HIV/AIDS vaccines;
- Differential diagnostics of vaccine-induced and HIV-induced immune response;
- Cohorts of HIV-seronegative volunteers formation.

Reasons of Willingness and Refusal to Participate in Clinical Trials of Vaccine VICHREPOL

Reasons to participate:

Help to HIV-infected people (65%)

Contribution to scientific investigations on development of HIV/AIDS vaccine (35%)

Possibility of immune protection against HIV infection (18%)

Free insurance and medical observation, payment (4%)

Reasons to refuse:

Doubt of vaccine safety and Afraid to receive HIV infection through vaccination (61%)

Afraid of possible adverse side effects (30%)

Afraid of false HIV seropositivity (15%)

Impossibility to perform the trial protocol (7%)

Low payment (2%)

Unexplained reasons (15%)

VICHREPOL clinical trials

Group	1	2	3	4	5
Immunizing dose (mcg/person)	2,5	5	10	25	50

Immunization

Weeks after the 1st injection	0	4	6	12	14	24	25	28	36	48
Immunization	I	II		III		IV				

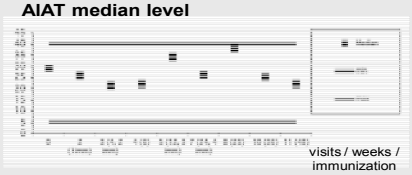
End points:

- Safety and tolerability
- Immunogenicity

Main biochemical indications during immunization of volunteers with VICHREPOL vaccine

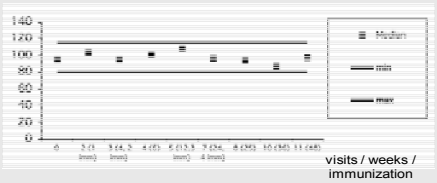
All tested indications of safety were in normal limits

AlAT median level



AsAT median level

Creatinine median level

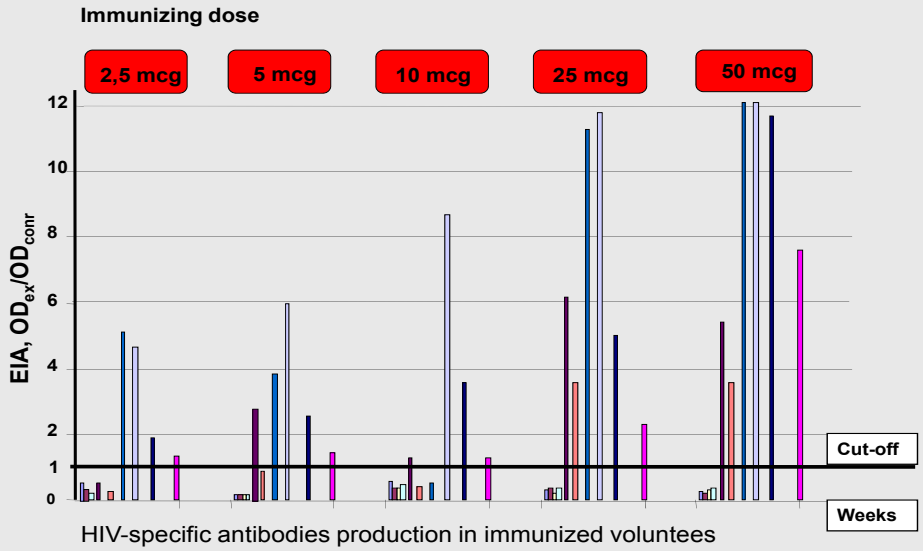


Safety and tolerability of VICHREPOL vaccine

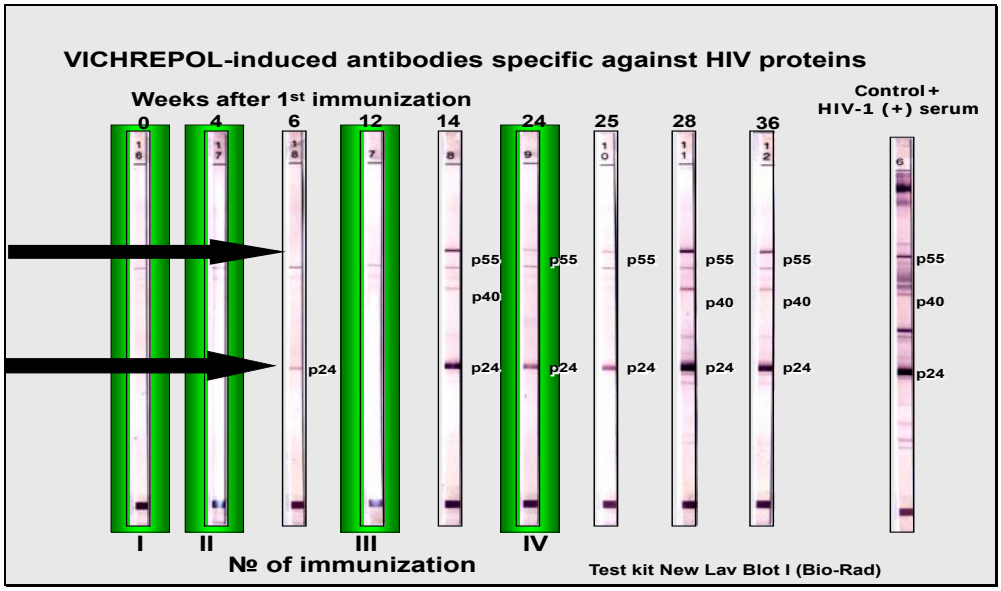
- After immunization of volunteers with VICHREPOL vaccine adverse side effects or unliked changes in clinical and biochemical indications were not detected.
- Vaccine has good safety profile and tolerability, is apyrogenic, no local inflammatory reactions were detected.

So, VICHREPOL vaccine in doses 2.5, 5, 10, 25, 50 mcg (protein) can be characterized as safe and tolerable.

Immune response induced by VICHREPOL depends of immunizing dose



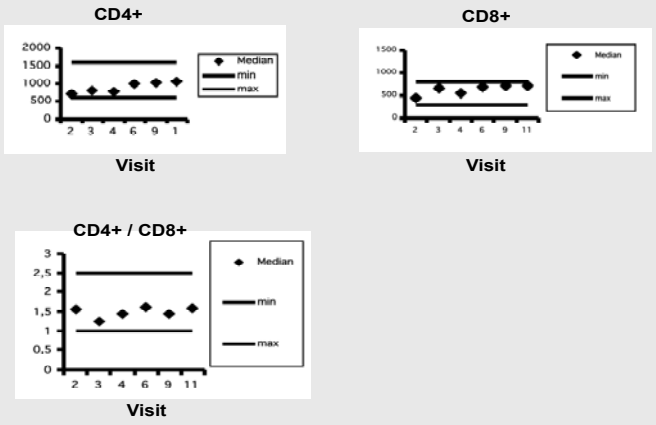
HIV-specific antibodies production in immunized voluntees



Titers of VICHREPOL-induced antibodies against antigens rec(24-41), rec p24 и rec gp41 in immunized volunteers

Antigen	Titers of antibodies (min – max)	Titer GeoMean (min – max)
rec(24-41)	1:10 – 1:320	10 – 100,79
rec p24	1:10 – 1:160	10 – 80
rec gp41	1:10	10

Dynamics of CD4+ T cells, CD8+ T cells and CD4+/CD8+ ratio during immunization with VICHREPOL vaccine



VICHREPOL vaccine immunogenicity

- **Vaccine VICHREPOL induced HIV-specific antibodies in immunized volunteers**
- **Immune response increased with increasing dose of vaccine**
- **Maximal immune response was achieved after 4th immunization**
- **Immunization with vaccine VICHREPOL didn't lead to change the T cell immunity indicators**

HIV/AIDS vaccine VICHREPOL trials: Transition to phase II

- Testing of immunogenicity, further testing of safety and tolerability
- Cohort: > 1000 HIV-seronegative healthy volunteers (stability >87%)

HIV Vaccine Acceptance

- Ready for vaccination in general population – 59,7%
- Ready for vaccination in risk groups – 78,7%

- Ready to participate in clinical trials (general population) - 15%
- Ready to participate in clinical trials (risk groups) - 60%

Acknowledgements:

- **R.M.Khaitov**
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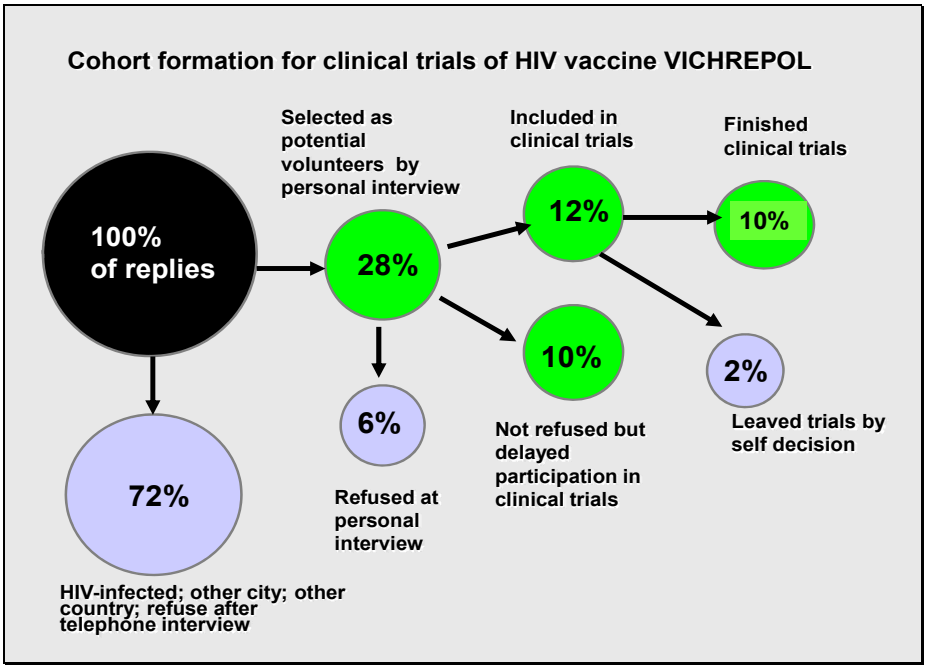
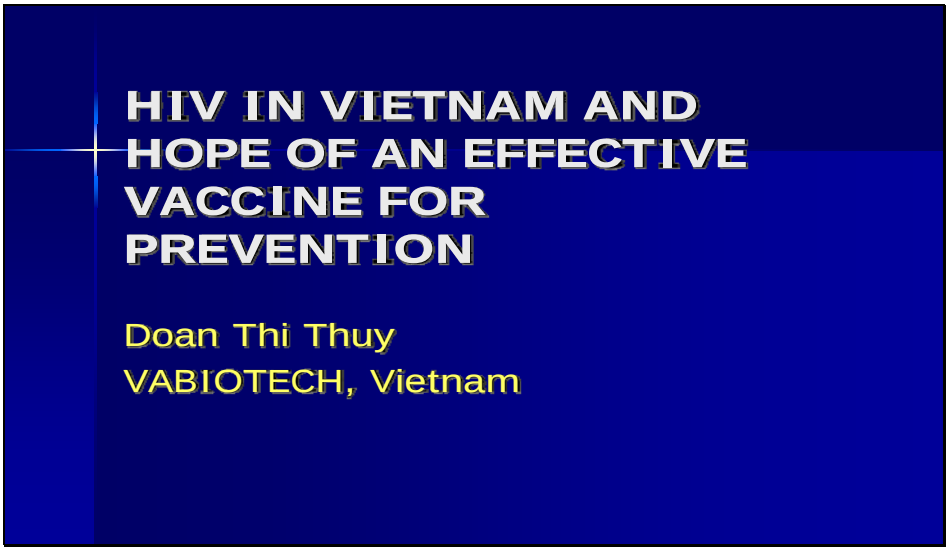
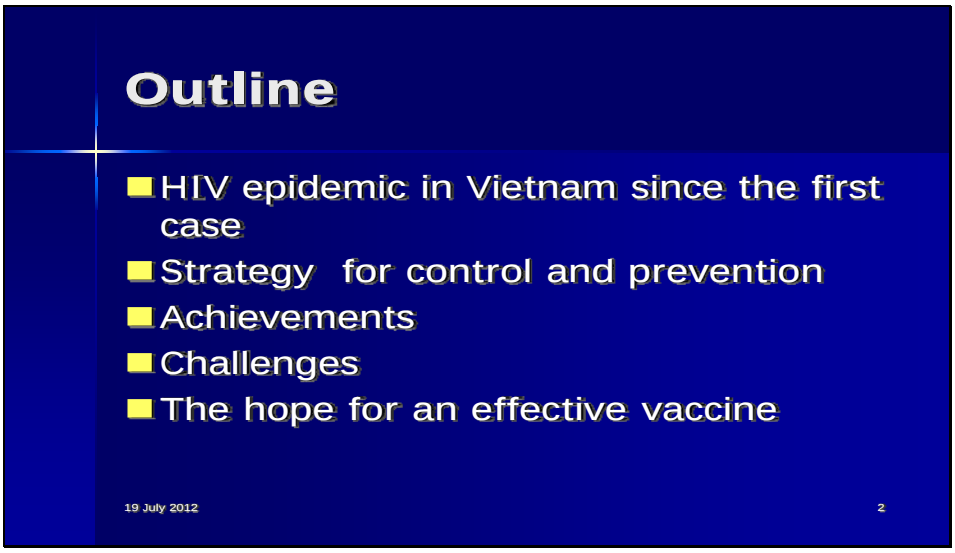
- **I.A.Nikolaeva**
- **S.V.Korobova**
- **A.F.Shevalier**
- **V.A.Gasanov**
- **G.V.Kornilaeva**
- **O.V.Pavlova**


Cohort formation for clinical trials of HIV vaccine VICHREPOL
Selected as potential volunteers by personal interview
Included in clinical trials
Finished clinical trials
100% of replies
28%
12%
10%
10%
2%
6%
72%
Not refused but delayed participation in clinical trials
Leaved trials by self decision
Refused at personal interview
HIV-infected; other city; other country; refuse after telephone interview

k) Annex 3


HIV IN VIETNAM AND HOPE OF AN EFFECTIVE VACCINE FOR PREVENTION
Doan Thi Thuy
VABIOTECH, Vietnam


Outline
HIV epidemic in Vietnam since the first case
Strategy for control and prevention
Achievements
Challenges
The hope for an effective vaccine
19 July 2012
2

HIV in Vietnam

- The HIV epidemic in Vietnam is classified as concentrated phase, with high prevalence among high risk populations.
- These include injecting drug users (IDUs), female sex worker (FSWs) and men who have sex with men (MSM). The first case of HIV infection was reported in December 1990 in Ho Chi Minh city.
- By 1992, only 11 cases has been reported, but from 1993 the number of infections increased rapidly.

Strategy and Action

- In order to push back a potential generalized epidemic government has issued **"Law on HIV/AIDS prevention and control"** and **"National Strategy on HIV/AIDS to 2010 and Vision 2020"**.
- Nine Programmes of Action were called for implementation the Strategy:

- Programme 1: HIV Prevention through Information, Education and Communication (IEC) and Behavior Change Communication (BCC).

19 July 2012 6

- Programme 2: Harm Reduction Prevention targeting high risk populations

19 July 2012 7

- Programme 3: Care and Support for People Living with HIV

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- Programme 4: HIV Surveillance and Monitoring and Evaluation (M&E)

19 July 2012 9

- Programme 5: Access to HIV Treatment including Antiretroviral Drugs.

19 July 2012 10

- Programme 6: Prevention of Mother to Child Transmission (PMTCT)

Programmes

- Programme 7: Management and Treatment of Sexually Transmitted Infections (STI).
- Programme 8: Safe Blood Transfusion.
- Programme 9: Capacity Building and International Cooperation Enhancement.

Achievements

- Twenty years Vietnam has ongoing efforts in the fight against HIV/AIDS and achieved many important results. The HIV epidemic tend to slow down and not rise as fast as previous years.
- And Vietnam has achieved National targets for control HIV infection rates in communities of below 0.3%.

Achievements

- Take sample HIV infection nationwide in 2011 as follows:
  - The numbers of detected cases of HIV tests reported in the year: 14,125.
  - The numbers of reported AIDS patients in the year: 6,432.
  - The numbers of AIDS patients reported in the year of death: 2,413.

19 July 2012 14

Achivements

  - Total HIV cases are currently alive: 197,335.
  - Total number of AIDS patients are still alive: 48,720.
  - Total number of HIV infections were fatal: 52,325.

19 July 2012 15

Challenges

- However the situation of HIV infection is complicated and still contains the risk factors outbreak. The potential transmission from IDU partners and from migrant population to the general female population.
- From above - mentioned information we can recognize that the fighting against HIV/AIDS still face many difficulties.

19 July 2012 16

The Hope of an Effective Vaccine

- Therefore the development of a safe and effective vaccine against HIV is critical and most comprehensive approach to pandemic control.
- Vaccines against HIV are being developed and they are in various phases of clinical trial but at present non has been proven effective because of greatest scientific challenges.

19 July 2012 17

The Hope

- The virus has developed multiple mechanisms to evade the body's defenses. Fortunately, researchers have made remarkable progress toward that goal in recent years.
- In 2009, a clinical trial in Thailand demonstrated for the first time that vaccine can prevent HIV infection.

19 July 2012 18

- Several preclinical studies of novel vectors for HIV vaccine have produced promising results.

The Hope

- These and other advances in HIV vaccine development have boosted optimism in the field about the prospects for a safe and effective vaccine.
- Therefore, vaccine is our best hope for prevention and control of HIV infection.

Thank You!

I) Annex 4

The Thai HIV Prime Boost Vaccine Trial (RV144) and subsequent studies:
key information from HIV vaccine trial in Thailand

APEC Workshop
HIV vaccines as a part of complex approach to AIDS prevention and control

Moscow, Russian Federation
4-5 July. 2012

Dr. Supachai Rerks-Ngarm
Principal Investigator, RV148/144/152
Department of Disease Control
Ministry of Public Health, Thailand

1

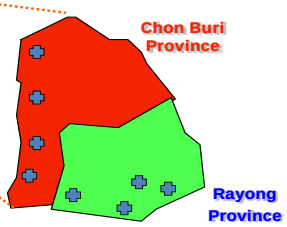
Thailand

Total population: **60,617,200**
- Male: 29,850,200
- Female: 30,767,000

Strong NGOs & CBOs

Health care infrastructure:
Regional/Provincial hospital @ provincial level
10-12 District hospitals in each province
10-15 Health centers in each district
10-15 VHV in each sub-district
10-15 HH per VHV

Rural 80%
Buddhist > 95%
Literacy >95%



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RV144 Trial Objectives

- To determine whether immunization with ALVAC ®-HIV (vCP1521) boosted by AIDSVAX® B/E gp120 B/E protects Thai volunteers from HIV infection.
- To determine effect of immunization on viral load after inter-current infection.

Design

- Community-based, randomized, double-blind, placebo-controlled trial (vaccine: placebo 1:1)
- Volunteers: HIV negative, 18-30 years of age
- Excluded: chronic disease, pregnancy or breastfeeding
- 6-month period of study vaccinations
- HIV testing every 6 months for 3 years post-vaccination

3

Study Vaccines

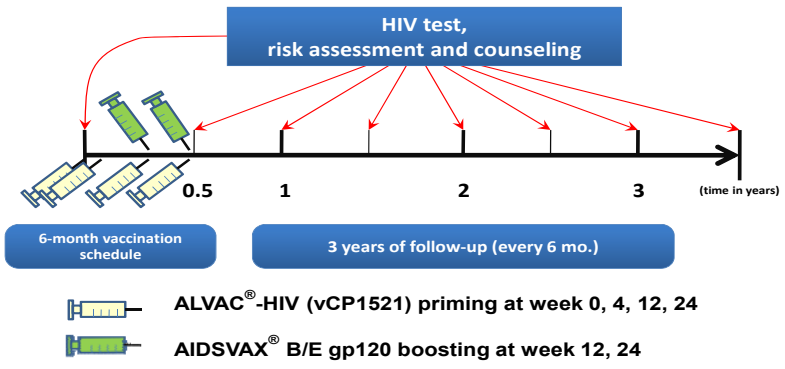
ALVAC®-HIV (vCP1521)

- Recombinant canarypox vector vaccine genetically engineered to express **HIV-1 gp120 (subtype E: 92TH023)** linked to the transmembrane anchoring portion of **gp41 (subtype B: LAI)**, and **HIV-1 gag and protease (subtype B: LAI)**.

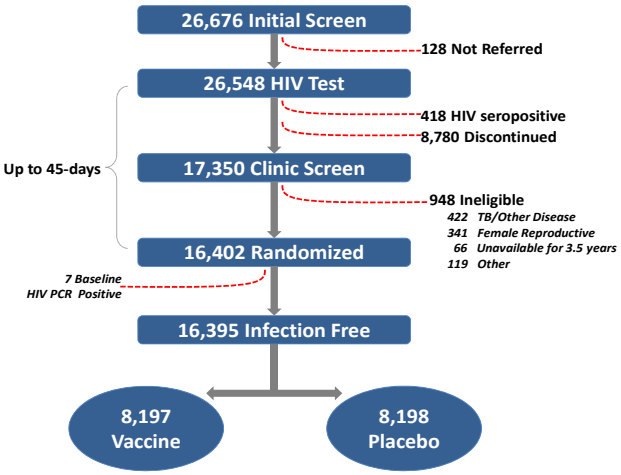
AIDSVAX® B/E

- Bivalent HIV gp120 envelope glycoprotein vaccine containing a **subtype E** envelope from the HIV-1 strain **CM244** and a **subtype B** envelope from the HIV-1 strain **MN**.

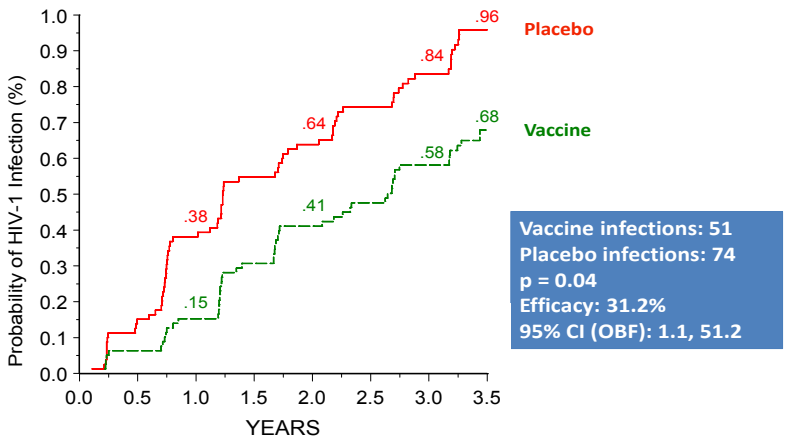
Vaccination and Follow-up Schedule



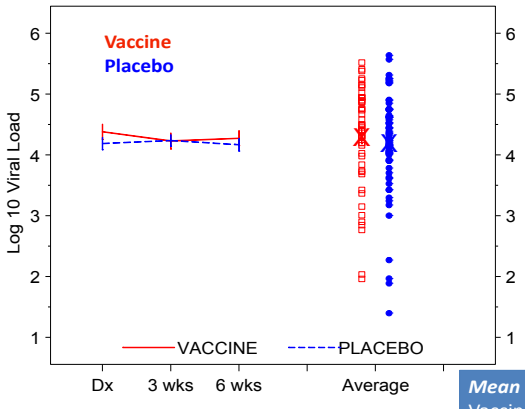
From Screening to Vaccination



Acquisition Endpoint: Modified Intent-to-Treat (mITT)



Early Viremia Endpoint

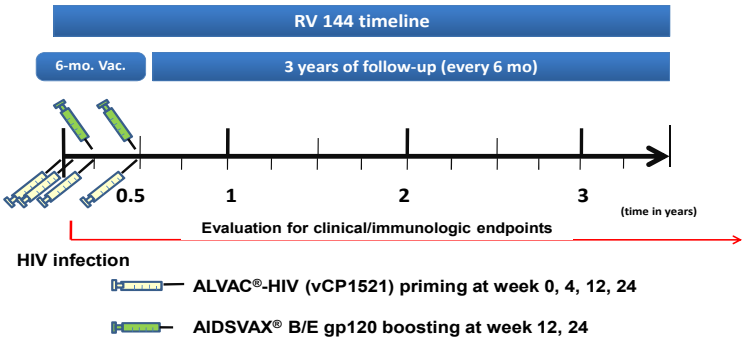


Mean Viral Load
Vaccine recipients: 4.3 $\log_{10}$
Placebo recipients: 4.2 $\log_{10}$
p = NS

Summary

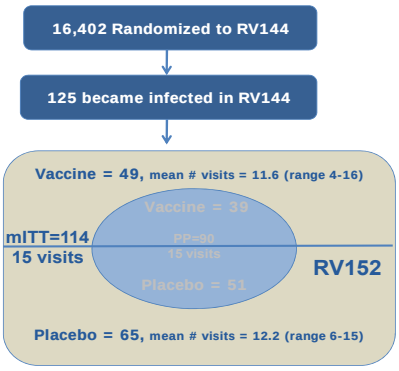
1. The observed vaccine efficacy in the mITT analysis was 31.2% [p = 0.04, 95% CI (OBF) 1.1, 52.1].
2. PP and mITT results were qualitatively consistent.
3. There is no difference in early viremia between vaccine and placebo recipients.
4. The vaccine regimen is safe and well tolerated.
5. Behavioral risk was the same in vaccine and placebo groups.

RV 152 in relation to RV 144



RV 152 Timeline (every 3 mo. after infection)
Concurrent with RV 144

From RV144 to RV152



Primary Composite Endpoint

CD4 < 350 cells/μL (verified by two measurements at least two-week apart)

AIDS-defining illness (first documented event)

Initiation of ARVs (per Thai National Guidelines)

Secondary Objectives

Long-term clinical outcomes—progression of disease (AIDS-defining illness and death)

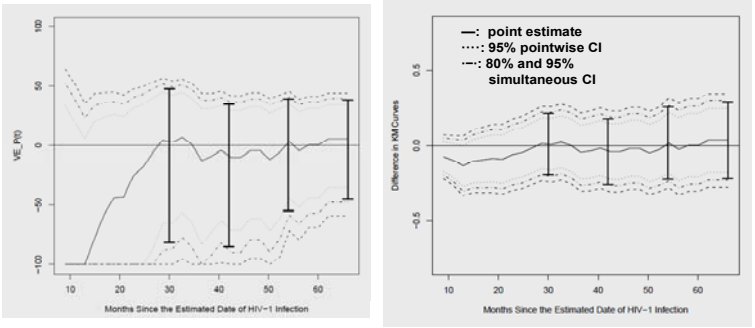
Longitudinal trajectory of pre-HAART $CD4^+$/viral load

Mucosal viral load at visit 1

Vaccine effect on the primary composite endpoint in mITT cohort over time

(a) Estimated vaccine effect on disease progression

(b) Estimated survival probability difference

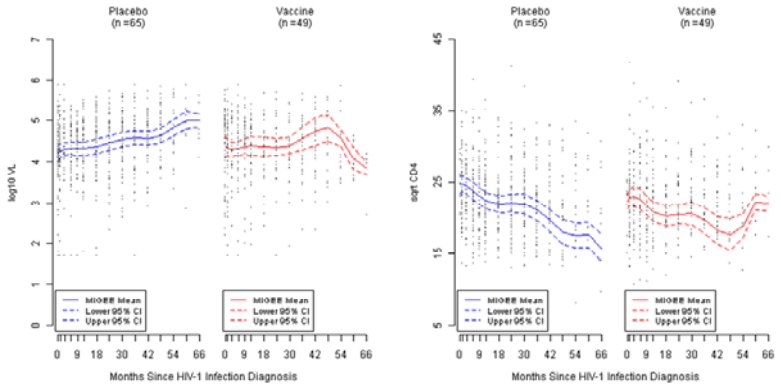


***The primary analysis assesses the vaccine effect at the fixed time-points 30, 42, 54, and 66 months after the estimated date of HIV-1 infection, with 95% simultaneous confidence intervals (bold vertical segments are simultaneous 95% confidence intervals for the four pre-specified post-infection time-points, 30, 42, 54, 66 months).**

Pre-HAART mean viral loads and mean CD4+ T cell counts diverge at 48 month after HIV-1 infection diagnosis (mITT cohort)

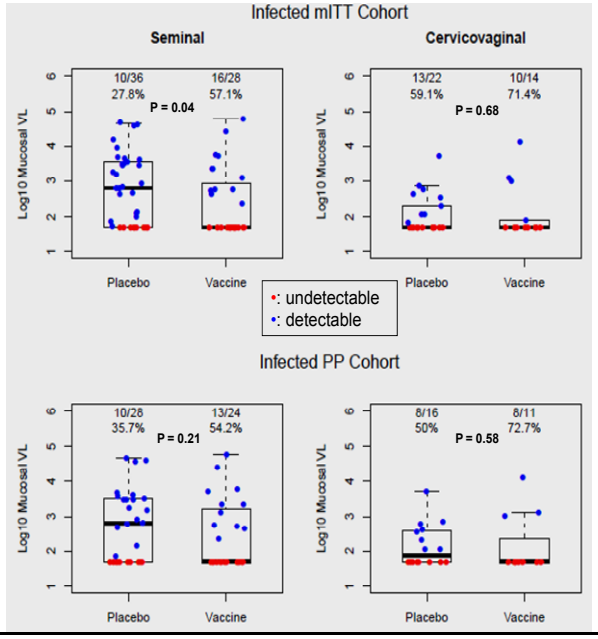
(a) pre-HAART $\log_{10}$ viral loads

(b) pre-HAART square-root CD4+ T cell counts



This slide shows scatter plots of pre-HAART viral loads and CD4 counts between vaccine and placebo recipients during long term follow up; there was no difference. However, the curves appear to diverge at 48 months. This effect is unknown as the numbers were too small.

Lower pre-HAART viral loads in mucosal fluid in vaccine compared to placebo recipients



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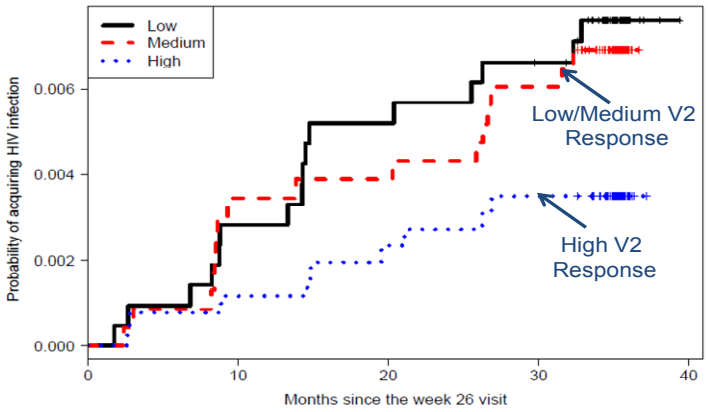
Summary

- The vaccine regimen is safe
- There was no evidence of a vaccine effect on the composite endpoint
- No difference between vaccine and placebo plasma viral load and CD4 count during long term follow-up
- There was divergence in viral load and CD4 trajectory between vaccine vs. placebo recipients beyond month 48
- Vaccination was associated with lower viral loads in the seminal fluid (p=0.04); [P14.13 LB]

Immune Correlate study from RV144:

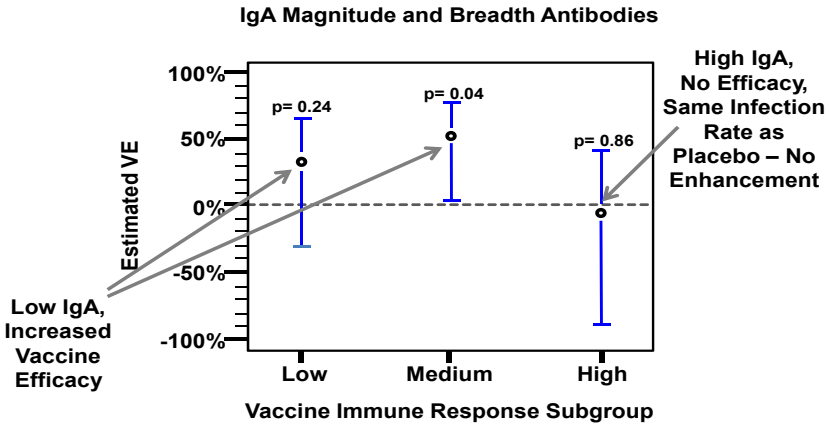
gp70 V1-V2 Antibody Levels Inversely Correlate with the Rate of HIV Infection



Logistic regression model accounting for the sampling design:
Estimated relative risk = 0.57 per sd increment in V2 response (p=0.015)

43% lower infection rate per sd increase

Comparison of Infection Rate and Vaccine Efficacy Between Vaccinees and Placebo Recipients in the RV144 ALVAC-HIV, VAXGEN Trial



Summary

- We have two correlates of risk that associate with infection rate in vaccinees in RV144.
- IgG antibodies that bind to scaffolded=V1V2 recombinant protein correlated *inversely* with infection rate. (Higher V1V2, *lower* infection rate)
- Env binding plasma IgA correlated *directly* with infection rate. (Higher IgA to Env, *higher* infection rate)

18

Conclusion

- The vaccine regimen is safe
- The observed vaccine efficacy in the mITT analysis was 31.2% [p = 0.04, 95% CI (OBF) 1.1, 52.1].
- There is no difference in early viremia between vaccine and placebo recipients.
- There was no evidence of a vaccine effect on the composite endpoint
- No difference between vaccine and placebo plasma viral load and CD4 count during long term follow-up
- Vaccination was associated with lower viral loads in the seminal fluid (p=0.04); [P14.13 LB]
- The pre-specified primary analysis generated the following hypotheses:
  - High V1V2 responses protect from HIV-1 infection
  - High IgA Env responses interfere with protection from HIV-1 infection
    No evidence for enhancement.

19

ACKNOWLEDGEMENTS

•RV144 and RV152 volunteers and community members

•Participants in Phase I/II ALVAC and AIDSVAX B/E trials

m) Annex 5

Rationale for HIV vaccine design

Sidorovich I.G., Nikolaeva I.A

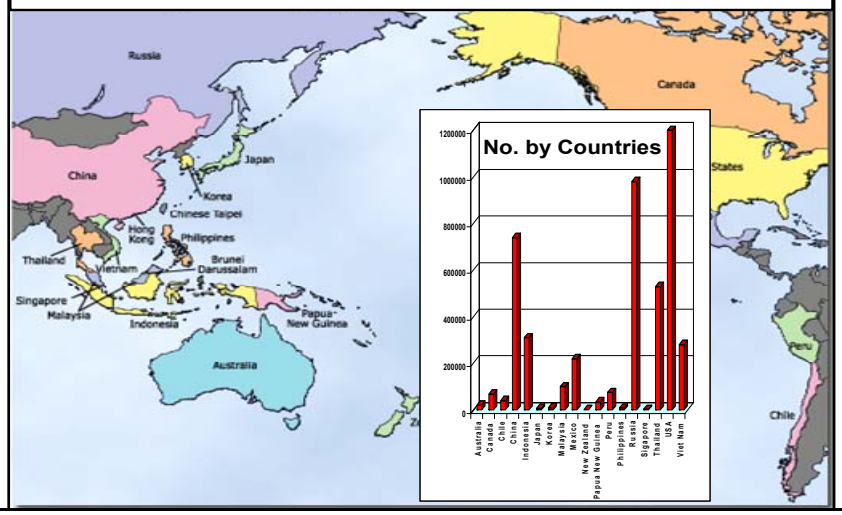
National Research Center
Institute of Immunology
Federal Medical-Biological Agency
of Russia

Number of HIV cases

	1988	2010
Worldwide	2.3 to 2.8 mln (WHO est.)	34 000 000* living with HIV
Uganda	~20-25% of population	~6% of population
USA	~1 000 000 (est.) **(83 000 cases of AIDS reg.)**	~1 000 000 (est.)
Russia	<100	650100**,

*2011 UNAIDS World AIDS Day Report
**registered on 31 December 2011(Russian Federal AIDS Center Report)

Estimated People Living with HIV in APEC Economies 4,600,000 [3,450,000-5,750,000] (UNAIDS Report, 2010)

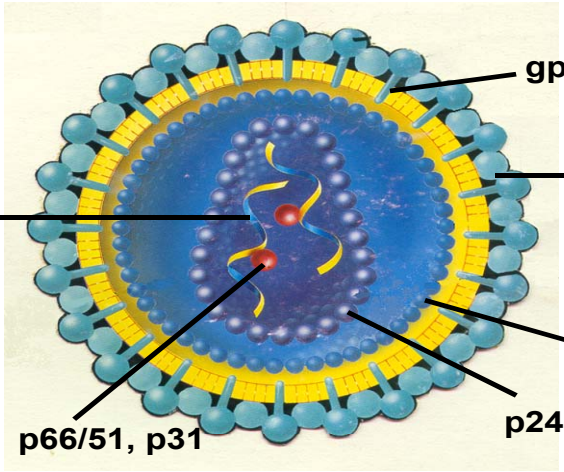


30 years of HIV vaccine research

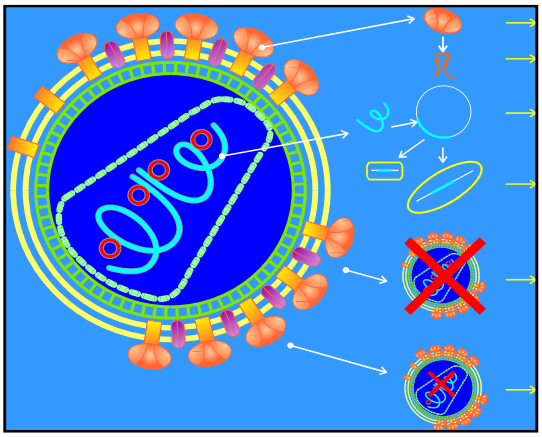
- **1981 – syndrome described**
- **1983 – causative infectious agent identified *(Rober Gallo, Luc Montagnier)***
- **1984 – data on complete HIV genome available: laboratory diagnostics**
- **1987 – first HIV vaccine clinical trial started in USA**

Well, if you have virus – you think that you can move straightforward to discovery of vaccine???

HIV virion



HIV vaccine approaches



Immune correlates

- **What type of immune response can protect against HIV infection or progression to AIDS?**
  - **Humoral immunity (neutralizing Ab) (against free virus)**
  - **Cell-mediated immunity (CTLs, T helper cells) (against infected cells)**
  - **Mucosal immunity**
  - **ADCC**
  - **Combination of all ?**

Different vaccine concepts are explored

targeting different types of immune response(s)

Most effective vaccines use live attenuated virus

But this is not the case for HIV

- **We cannot use live or attenuated virus (safety reasons)**
- **No adequate experimental model (animals)**

Problems with HIV infection

- Nature of HIV: infectious virus + oncogenic virus, integration to the genome of the cell
- Target – immune system
- No cases of recovery.
- We don't know immune correlates capable to provide protective immune response
- No adequate experimental model (animals): therefore, only large scale clinical trials can prove that vaccine efficient
- Variability

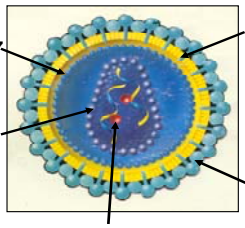
For safety reasons we can't use live attenuated virus.
We must use recombinant products, coping HIV antigens

Hence, we need to use adjuvants

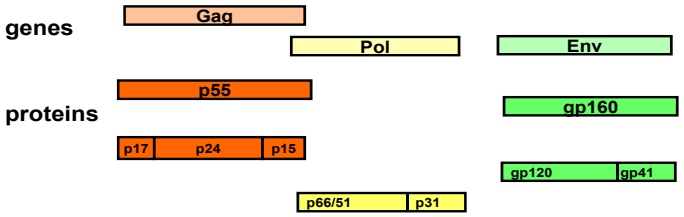
The First Russian HIV Vaccine VICHREPOL

Antigen desired

•Internal proteins are relatively conservative.
•Internal and envelope proteins: CTL&Th epitopes

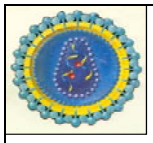


•Envelope proteins (gp120 & gp41) induce neutralizing ABs



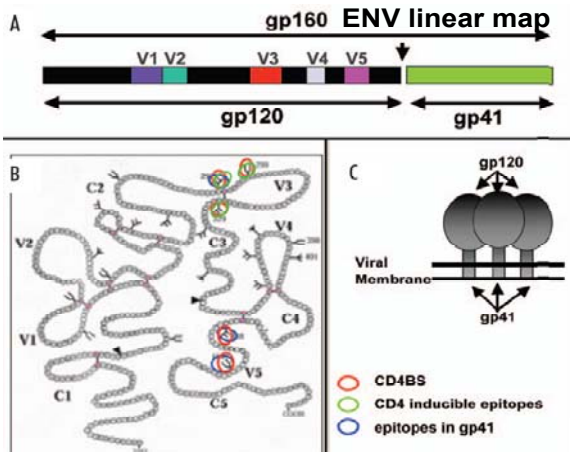
Antigen desired

- **HIV envelope is the primary target for neutralizing antibodies in HIV–infected persons, while most CTL and helper epitopes are located within relatively conserved domains of *gag*–coded proteins.**
- **Rec(24-41) comprises both *gag*– and *env*–coded proteins, conserved among HIV subtypes.**

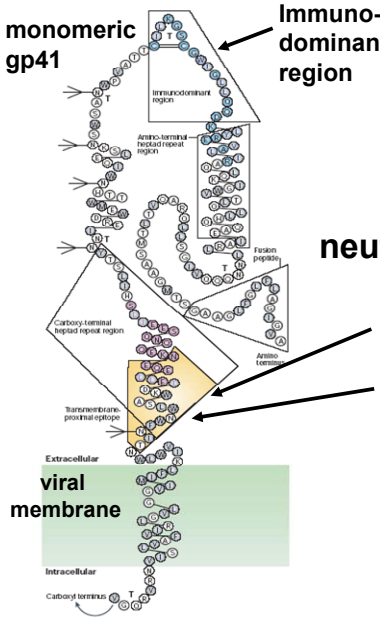


Targets for immune response

monomeric gp120



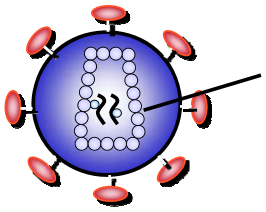
Srivastava et al, Human Vaccines, 1:2, 45-60, 2005



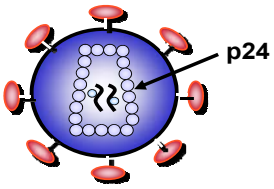
Antigen desired

linear epitopes for broadly neutralizing AB located at gp41

- NEQELL**ELDKWA**SLWN (2F5)
- KGWNWFDITNWGK

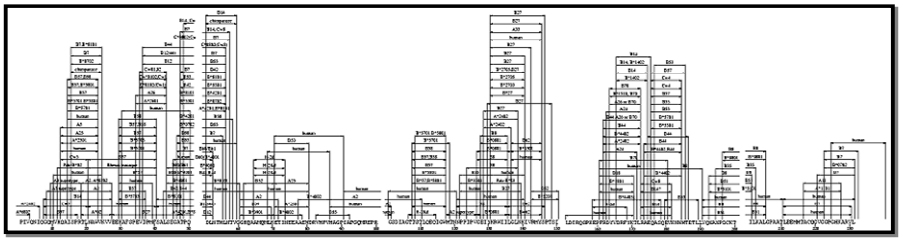


Antigen desired



- GAG specific immune responses correlate with successful control of HIV in infected individuals
- GAG relatively conservative

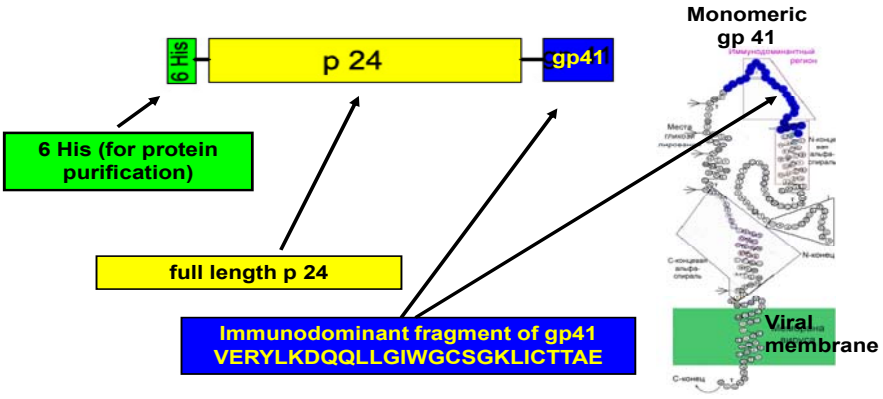
p24 CTL epitopes location



HIV1 p24 aa sequence

rec (24-41)

full length p 24 and fragment of gp 41



Adjuvant

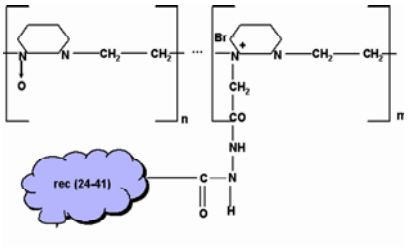
- Synthetic polymer polyoxidonium (PO) (N-oxide derivative of poly-1,4-ethylenepiperazine) enhances immune response
- Approved for use in humans *per se* & as a part of vaccines and drugs formulation
- Formulation of commercially available large-scale product influenza vaccine Grippol includes PO as an adjuvant

VICHREPOL

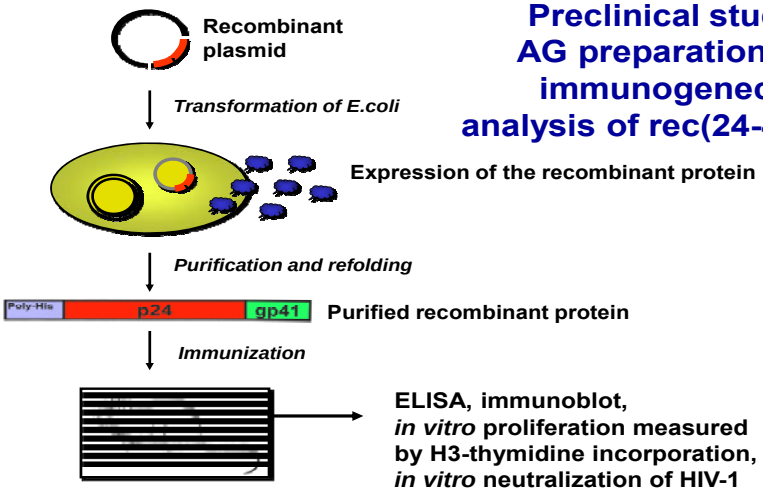
chimeric recombinant protein rec(24-41)

immunomodulator polyoxidonium (PO)

structure of VICHREPOL (protein-PO binding region)

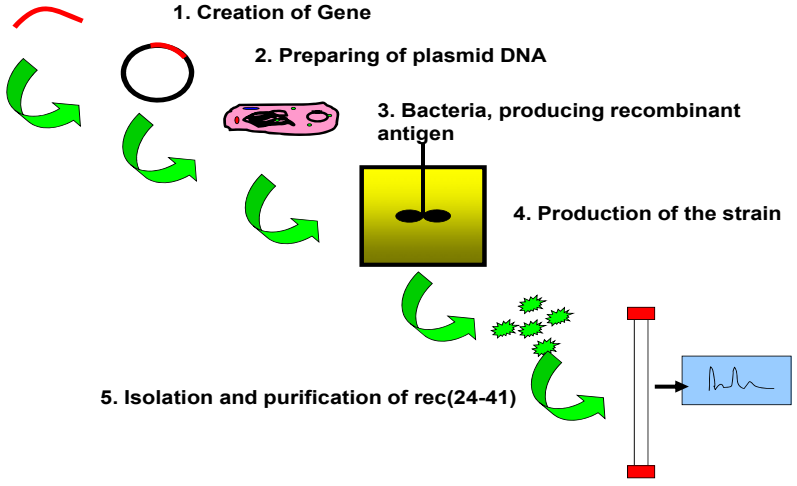


Preclinical study: AG preparation & immunogenecity analysis of rec(24-41)



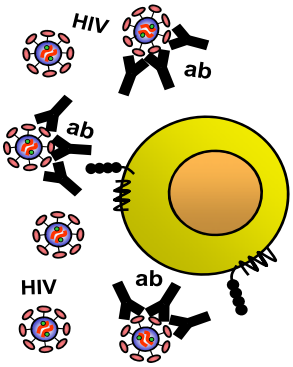
ELISA, immunoblot,
in vitro proliferation measured by H3-thymidine incorporation,
in vitro neutralization of HIV-1

Stages of rec(24-41) preparation



Summary

VICHREPOL is safe and immunogenic product



Search of immune correlates

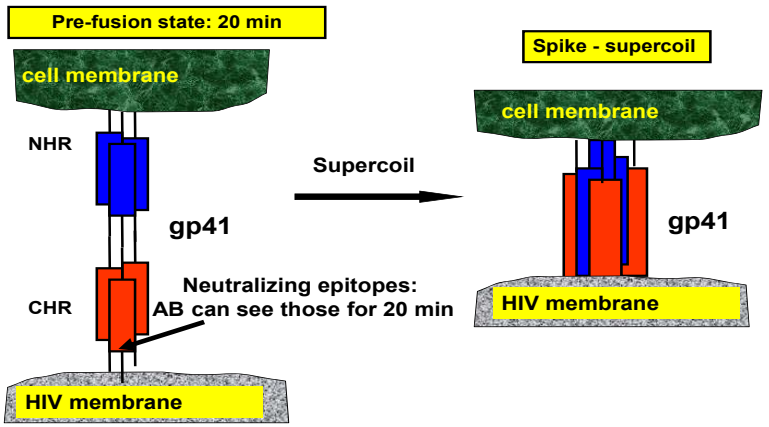
- Elite controllers
- Samples from RV144 trials
- Learning from live attenuated SIV (macaques)

Search of Target

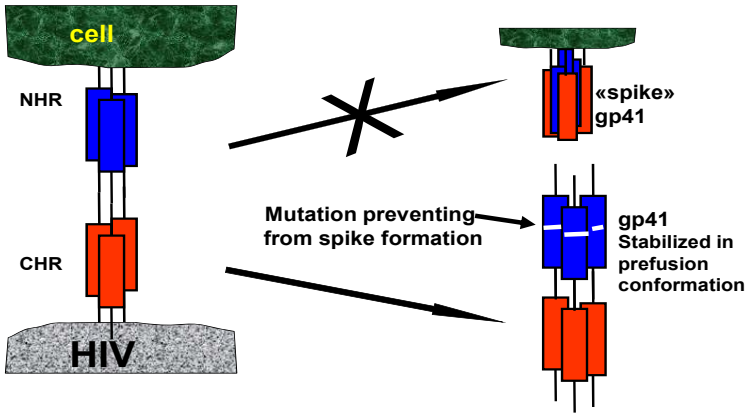
- Envelope protein trimer: complex of proteins on the surface of HIV. Problem: we need to fix short-living intermediate stage during virus entry.
- Reverse engineering of vaccine immunogens (from broadly neutralizing antibodies to antigen)

Nearly two dozen broadly neutralizing antibodies were isolated from HIV infected donors. This shows that immune system does is capable of doing this. Thus, problem is solvable in due time.

Conformational changes during interaction of gp41 with cell



Trimer of gp41 ectodomain can be stabilized in prefusion state



"Old news": time required for vaccines' implementation from discovery of causative agent to licensed vaccine

Causative agent/ disease	Causative agent discovered	Licensed vaccine (USA)	Time (years)
Bordetella pertussis/pertussis	1906	1948	42
Poliovirus/poliomyelitis	1908	1955	47
Measles virus/measles	1953	1963	10
Hepatitis B virus/hepatitis	1965	1981	16
Haemophilus influenzae/meningitis	1889	1981	92
Salmonella Typhi/tiphoid fever	1884	1989	105
Varicella zoster virus/varicella	1953	1995	42
Rotavirus/diarrhea	1973	2006	33
Human papillomavirus/cervical carcinoma	1981	2006	25
HIV/AIDS	1983	–	29+
Plasmodium spp./malaria	1880	–	128+

AIDS Vaccine Blueprint, 2008

- More fundamental studies
- More cooperation
- Harmonization of efforts of our economies

Study Participants

- **Institute of Immunology & HIV Vaccine Trials Site (Moscow, Russia)**
  - R.Khaitov
  - I.Sidorovich
  - G.Gudima
  - I.Nikolaeva
  - S.Korobova
  - A.Chevalier
  - Yu.Gornostaeva
  - L.Trubcheninova
  - B.Pinegin
  - A.Chernousov
  - V.Gasanov
- **D.I.Ivanovsky Institute of Virology (Moscow, Russia)**
  - E.Karamov
  - G.Kornilaeva
  - T.Pavlova
- **DNA-Technology Corporation (Moscow, Russia)**
  - D.Trofimov
  - M.Boldireva
  - T.Petrova

Funding:

• **Russian National Research Program "Vaccines of the New Generation and Medical Diagnostic Systems of the Future"**

• **Federal Medical-Biological Agency, Ministry of Health, Russian Government (grants KV VICH-08, KV VICH-09, KV VICH-10)**

• **RF Ministry of Science and Education (GC 7094, 7095, 7059, 7060, 7061, 7147, 2232)**

Thank you for your attention!

n) Annex 6

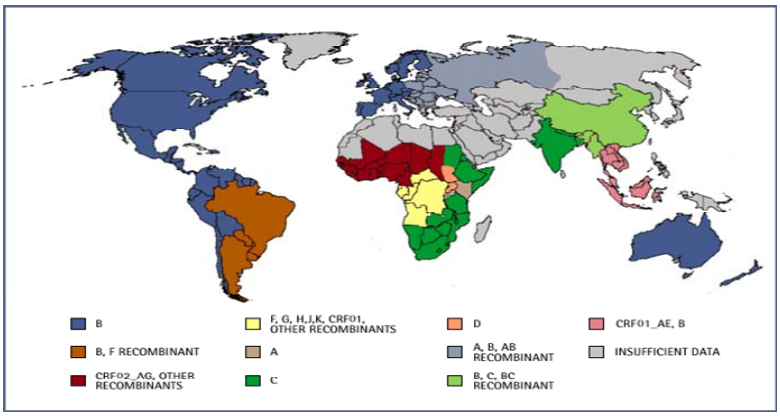
The potential of a low HIV prevalence country to participate in HIV vaccine clinical trial

HIV vaccines as a part of complex approach to AIDS prevention and control in APEC region
Moscow, Russian Federation
4-5 July, 2012

Rossana A. Ditangco, MD
Research Institute for Tropical Medicine
Metro Manila, Philippines

Issues in the conduct of HIV clinical trial

- Diversity of HIV in the region
- Large sample size
- Participant recruitment and retention- community involvement
- Ethical review board
- Regulatory



Molecular epidemiology of HIV in the Philippines

≈50% CRF_AE

≈ 50% B

- Need to further characterize subtypes (phylogenetic study)

Overall country prevalence < 1%

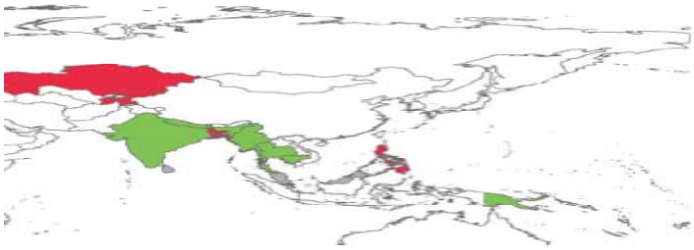
Prevalence Rates

Most-At-Risk Population	2007 # of HIV+	2007 Prevalence per 100,000	2009 # of HIV+	2009 Prevalence per 100,000
Injecting Drug Use	1	133	2	209
Registered Establishment Female Sex Workers	2	68	7	234
Freelance Female Sex Workers	1	44	15	542
Males who have Sex with Males	3	283	24	1,052
All MARPs	7	100	48	533

THIS IS IT! NEC TALKS ON HIV

63 countries reported.

The Philippines is one of only 7countries with increasing HIV cases



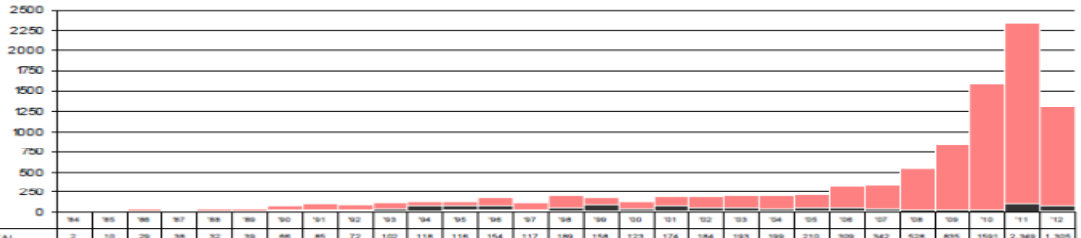
SCORECARD: INCIDENCE

Changes in the incidence rate of HIV infection, 2001 to 2009, selected countries

Increasing >25%	Stable	Decreasing >25%
Armenia	Angola	Belize
Bangladesh	Argentina	Botswana
Georgia	Belarus	Burkina Faso
Kazakhstan	Benin	Cambodia
Kyrgyzstan	Cameroon	Central African Republic
Philippines	Democratic Republic of the Congo	Congo
Tajikistan	Djibouti	Côte d'Ivoire
	France	Dominican Republic
	Germany	Eritrea
	Ghana	Ethiopia
	Haiti	Gabon
	Kenya	Guinea
	Lesotho	Guinea-Bissau
	Lithuania	India
	Malaysia	Jamaica
	Niger	Latvia
	Nigeria	Malawi
	Panama	Mali
	Republic of Moldova	Mozambique
	Senegal	Myanmar
	Sri Lanka	Namibia
	Uganda	Nepal
	United States of America	Papua New Guinea
		Rwanda
		Sierra Leone
		South Africa
		Suriname
		Swaziland
		Thailand
		Togo
		United Republic of Tanzania
		Zambia
		Zimbabwe

Source: UNAIDS Global Report 2010

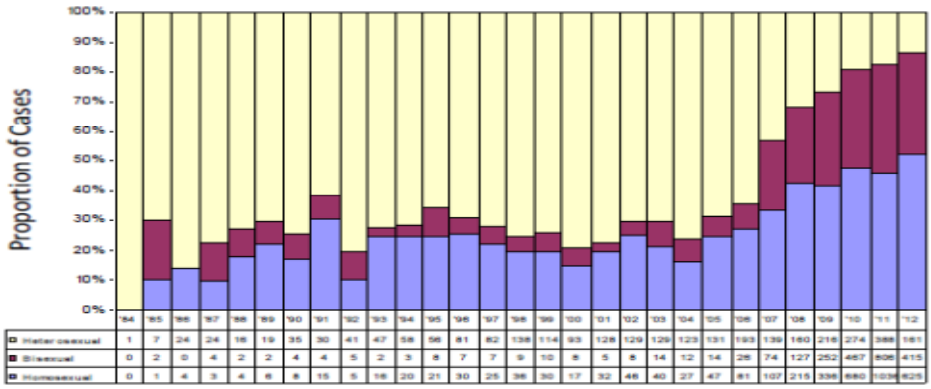
Number of HIV/AIDS Cases Reported in the Philippines by Year, Jan 1984 to May 2012 (N=9,669)



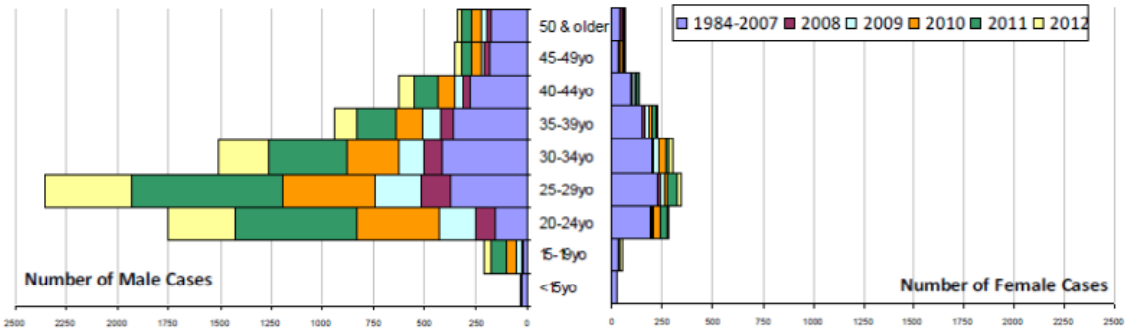
	'84	'85	'86	'87	'88	'89	'90	'91	'92	'93	'94	'95	'96	'97	'98	'99	'00	'01	'02	'03	'04	'05	'06	'07	'08	'09	'10	'11	'12
TOTAL	2	10	29	38	32	39	66	85	72	102	118	116	154	117	189	158	123	174	184	193	199	210	309	342	528	835	1591	2,349	1,305
Asymptomatic	0	6	18	25	21	29	48	68	51	64	61	65	104	94	144	80	83	117	140	139	160	171	273	311	506	804	1583	2,241	1,243
AIDS	2	4	11	13	11	10	18	17	21	38	57	51	50	23	45	78	40	57	44	54	39	39	36	31	22	31	28	108	62
Death	2	4	10	12	9	8	15	15	13	11	19	24	27	10	16	17	9	20	11	11	8	16	18	10	7	1	3	*19	9

*Nine initially asymptomatic cases reported in 2011, died due to AIDS that same year.

Proportion of Types of Sexual Transmission, Jan 1984–May 2012



Comparison of the Distribution of Male and Female HIV Cases by Age-Group and Certain Highlighted Years



Linking prevention and treatment, care and support for men who have sex with men
(The MSM Clinic Project)
Implementing agencies: Research Institute for Tropical Medicine
National AIDS/STI Prevention and Control Program
National Epidemiology Center
Strategies:
development of network of "change agents" among MSM
HIV antibody tests with same day result (for both positive and negative results)
integrated prevention, testing and care and support activities
discreet MSM sexual health clinic
Outreach programs (HIV summit)
research

Incidence of HIV in a cohort of men who have sex with men in Metro Manila

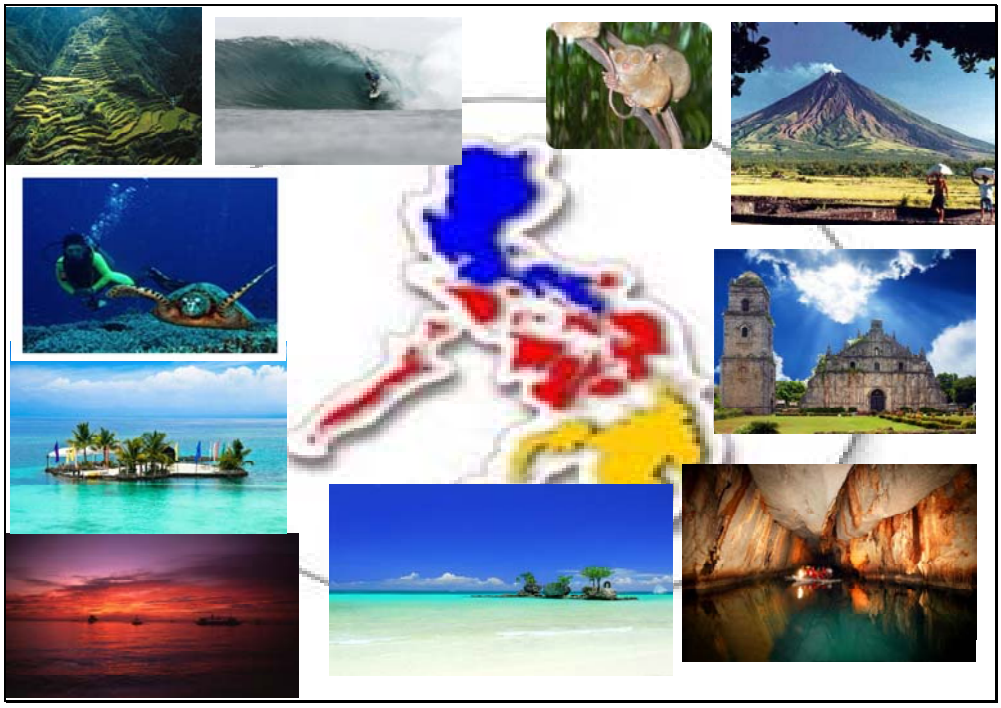
- Will recruit 600 MSM
- Will determine the incidence and prevalence of HIV and syphilis among MSM
- Will determine the prevalence of other sexually transmitted infections (STI)
- Will determine the subtype and presence of HIV drug resistance in chronic and acute HIV infection
- Will assess the retention rate in a cohort of MSM

Philippine potential to participate in HIV clinical trial

- Technological capability
- HIV characterization/phylogentic study- molecular biology laboratory
- HIV vaccine research and development – schistosoma vaccine on pre-clinical stage
- Vaccine development and storage facility

Philippine potential to participate in HIV clinical trial

- Network with community – recruitment and retention
- Ethical review board – institutional and national level
- Experience in local and international vaccine clinical trials
- regional clinical trial strategy- sample size, genetic diversity



o) Annex 7

Acceptance of HIV/AIDS vaccine in Russia

S.V. KOROBOVA

National Research Center Institute of Immunology,
Federal Medical & Biological Agency, Moscow

Actuality

«If we build it will they come?»

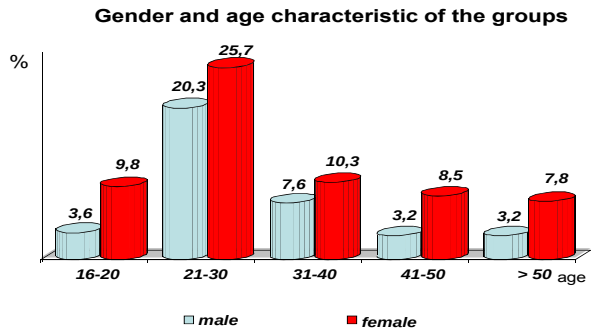
(Newman et al., 2004, AIDS Patient Care STDS, v.18, no.12, p.691-701)

THE HIV VACCINE DEVELOPMENT PROCESS REQUIRES A SERIES OF TRIALS IN DIFFERENT POPULATIONS AS WELL AS DETAILED PLANS FOR MANUFACTURING AND DISTRIBUTING A LICENSED PRODUCT

- the people's awareness about HIV/AIDS
- the willingness to participate in HIV vaccination

Respondents:

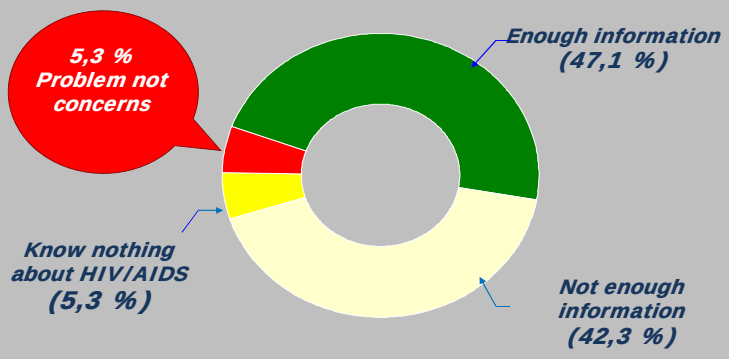
Moscow region 2011-2012



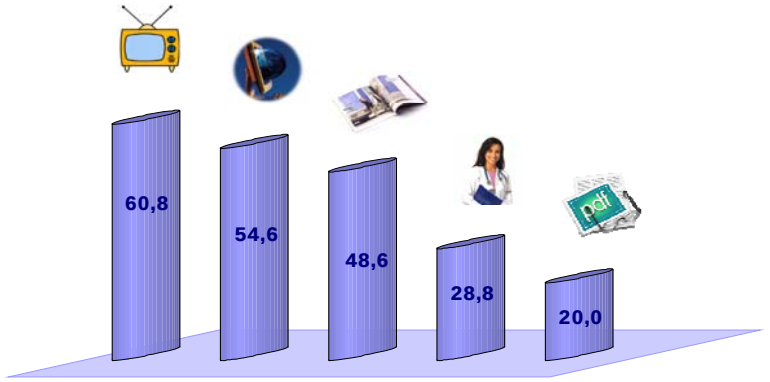
Question:
Concerns associated with HIV infection

Incurability	62,0 %
Quick distribution	43,3 %
High risk of infection	40,9 %

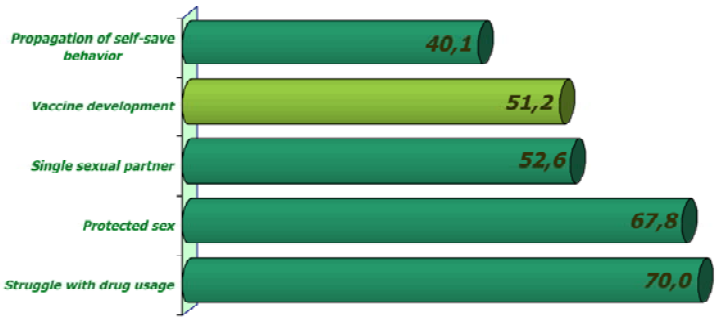
Question:
Awareness on HIV infection / AIDS



Sources of information about HIV/AIDS



Question: Possible ways of prevention and slowdown of HIV/AIDS pandemic?



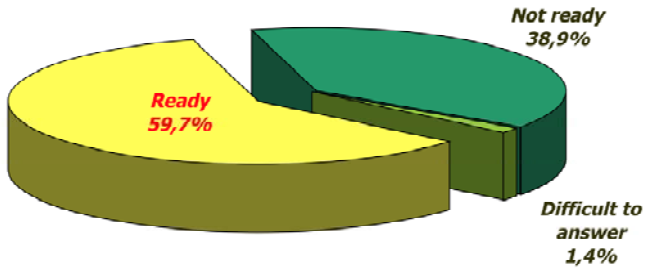
Question: Do you have a risk to be infected by HIV

30,5% - no risk of HIV infection

36,3% - risk of HIV infection is real

33,2% - difficult to answer

Readiness for vaccination against HIV/AIDS



Percent of "Ready-to-vaccination" persons is

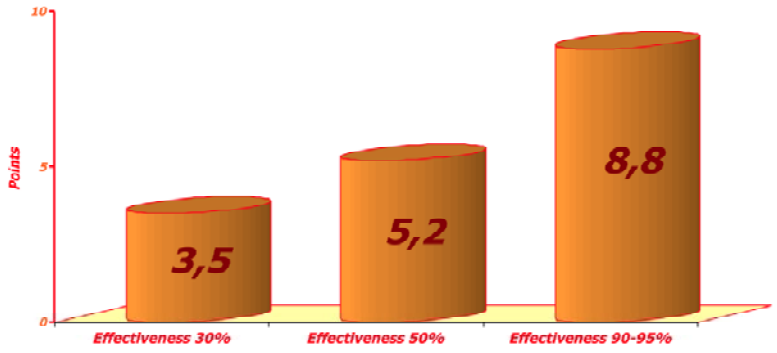
1,6 times higher in risk group of HIV infection

Readiness for vaccination against HIV/AIDS is lower in respondents with children:

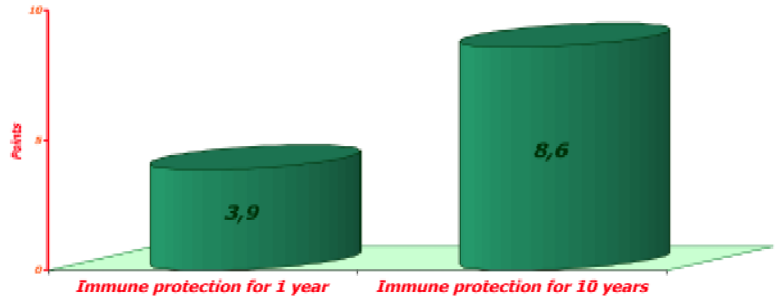
Not ready for vaccination
46,0 % - respondents with children
34,9 % - childless respondents

HIV/AIDS vaccine awareness is 1,4 times higher then readiness to vaccination

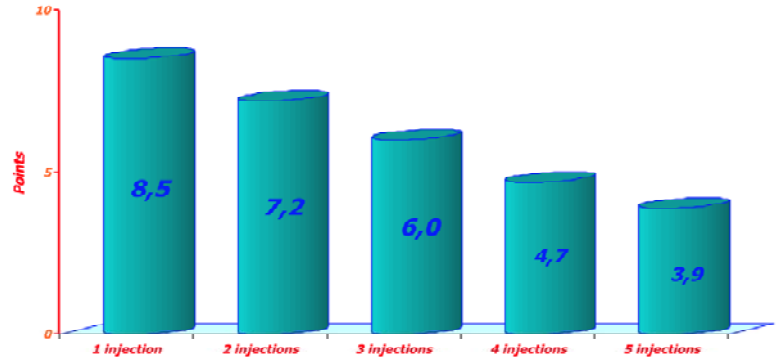
Readiness for vaccination against HIV/AIDS depends on vaccine efficacy



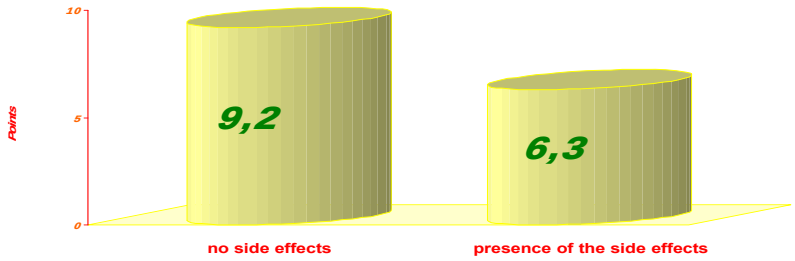
Readiness for vaccination against HIV/AIDS depends on duration of immune protection



Readiness for vaccination against HIV/AIDS depends on the number of injection in the course of vaccination



Readiness for vaccination against HIV/AIDS depends on possible side effects



Dependence of readiness for vaccination against HIV/AIDS on vaccine cost

25,0% - cost have no significance
21,3% - ready with free-of-charge vaccination
42,9% - ready with cost of vaccine <60 USD

The main factors influencing on the vaccine acceptance

- **Possible side effects**
- **Vaccine effectiveness against different HIV subtypes**
- **Permission for vaccine use in children and adolescents**
- **The cost of vaccine**
- **Number of injections in the course of vaccination**

Conclusions

Obtained data confirm trends mentioned in foreign studies, but readiness for vaccination against HIV/AIDS was lower in general population (59,7% vs 78%) and in population of risk of HIV infection (78,7% vs 95-97%)*

It is necessary to improve education programs directed to increase the awareness on development of HIV/AIDS vaccine, its safety and peculiarities.

*Suraratdecha et al., 2005, Health Policy, v.71, no.3, p.271-287.

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- National Research Center Institute of Immunology, Federal Medical & Biological Agency, Moscow

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Thank you for attention!

p) Annex 8

RESPONSES TO HIV AND AIDS IN MALAYSIA

BY
SHA'ARI NGADIMAN,
MD, MPH, EIP, AM
MINISTRY OF HEALTH MALAYSIA

Outline

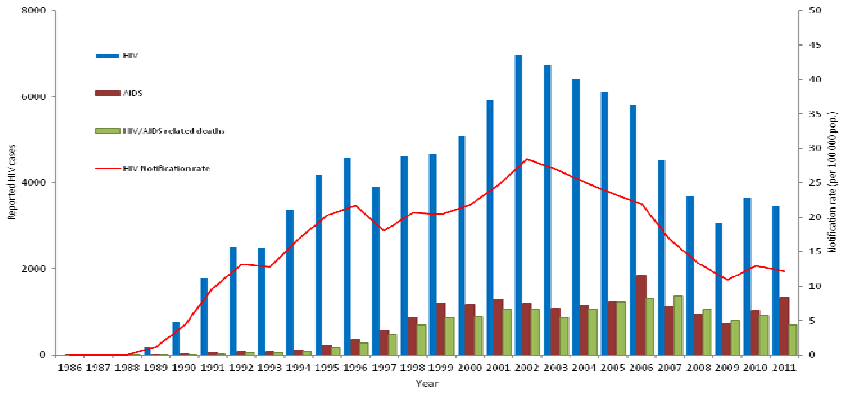
- Economy Profile
- Situational Analysis of Current HIV
  - HIV Burden
  - Who are at risk
- Policies
- Activities
  - Screening
  - Harm Reduction
  - MTCT
- What Next for 2011-2015
- Conclusion

ECONOMY PROFILE : MALAYSIA

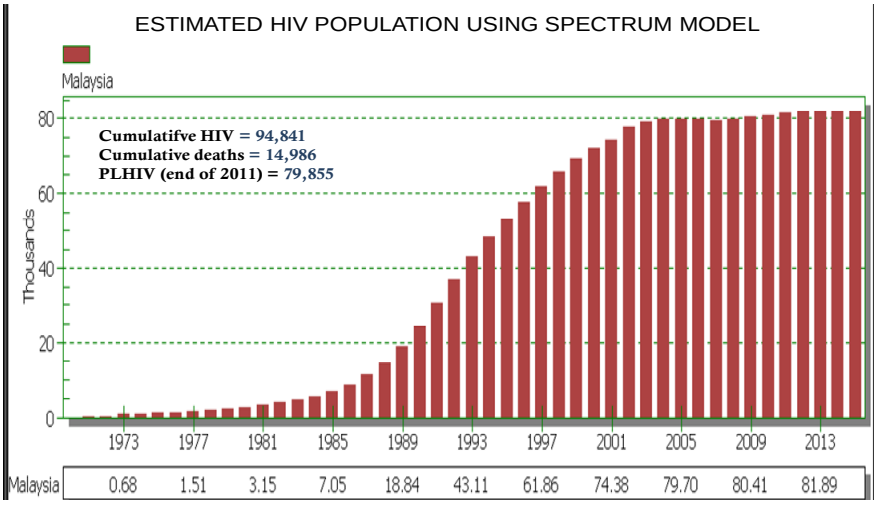
- Peninsular Malaysia and Sabah and Sarawak (Island of Borneo)
- Total land : 329 960 km sq
- Borders :
  - Land : Thailand, Indonesia and Brunei
  - Maritime : Singapore, Vietnam, Philippines
- Multiracial and multicultural
- Pop : 28 mil
- 13 states and 3 federal territories
- Health services :

  MOH hospital (130), Non-MOH Hosp (8), MOH Health Clinics (879),MOH MCH (90), MOH Spec Med Ins (6), MOH Community Clinics (1920), Private Hosp (209), Private Med Clinics (6307),

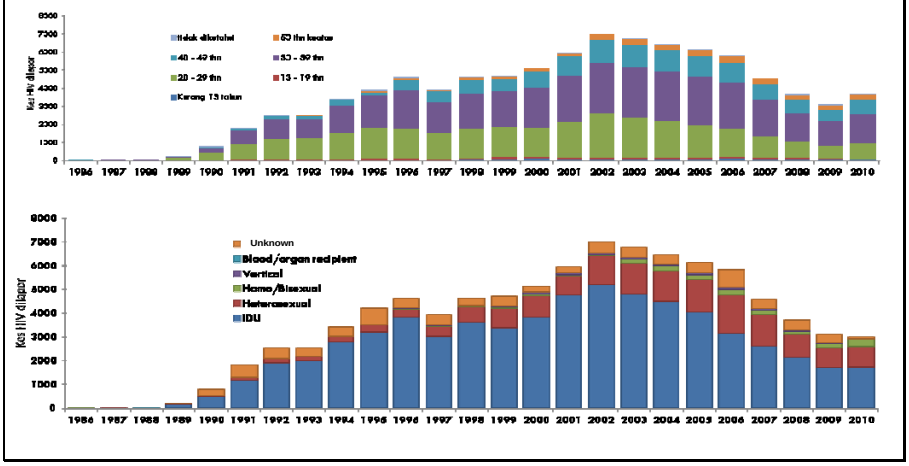
HIV, AIDS AND HIV/AIDS RELATED DEATHS NOTIFICATION IN MALAYSIA



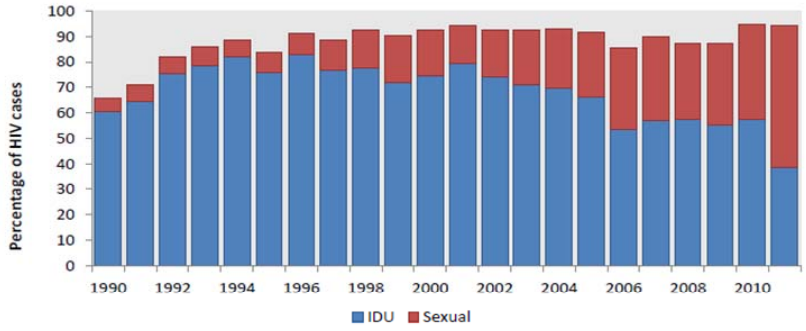
ESTIMATED HIV POPULATION USING SPECTRUM MODEL



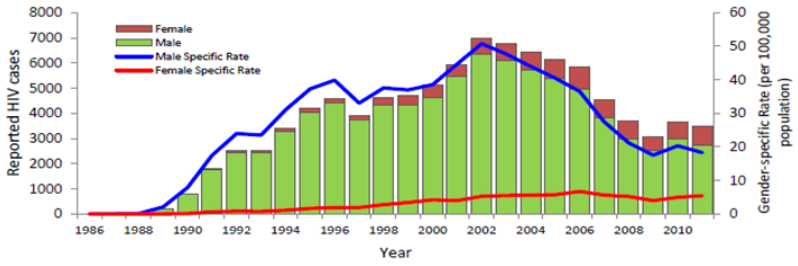
MALAYSIA HIV SITUATION



HIV - IDU and Sexual Transmission

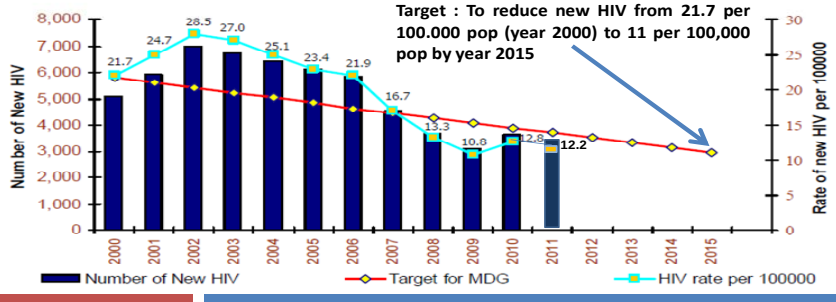


Gender-specific HIV Prevelance



NEW HIV CASE: TARGET FOR 2015

	YEAR							
	2008	2009	2010	2011	2012	2013	2014	2015
TARGET	**16.0**	**15.3**	**14.6**	**13.9**	**13.2**	**12.5**	**11.7**	**11.0**
ACHIEVED	**13.3**	**10.8**	**12.8**	**12.2**				



Turning Vision Into Reality

3Ps

- **Political Will,**
- **Policy**
- **Participation**

POLITICAL WILL

were given chemoprophylaxis for opportunistic infection and only 3 per cent received anti-retroviral therapy (ART). The proportion of HIV/AIDS patients under ART is relatively small because most eligible cases are followed up at hospitals. In order to increase coverage of ART in primary health care settings in line with WHO's 3 x 5 initiative, the MOH has increased the number of Family Medicine Specialists.

Enabling environment

Government engagement

The Malaysian government has adopted a multisectoral approach in its efforts to control HIV/AIDS and has increasingly supported measures to respond to the pandemic. This includes involving sectors other than health, such as education, information, and drug agency, as well as NGOs, in the many aspects of AIDS prevention, treatment, care, and support. A Taskforce on AIDS was set up before an AIDS case was first detected in the country in 1986.

In order to provide a more comprehensive response, an Inter-Ministerial Committee chaired by the MOH was established in 1992 to advised the Cabinet on policies, issues and strategic plans. A National Technical Committee was set up to streamline patient care, prevention and control, surveillance, laboratory services, training, and research. In addition, a multisectoral National Coordinating Committee on AIDS (NCCA) chaired by the Secretary-General of MOH was established to facilitate collaborative inter-sectoral actions on HIV/AIDS. The MOH has also facilitated the formation of the Malaysian AIDS Council (MAC) in 1993, an umbrella body of multisectoral NGOs involved in HIV/AIDS activities, in order to coordinate various outreach activities. The NCCA is supported by a state coordinating committee, with AIDS action teams being responsible for the programme at the district level.

NOTIFIABLE IN 1985

AIDS was gazetted as a notifiable disease in 1985. Under the Prevention and Control of Infectious Diseases Act 1988, all forms of HIV infections must be notified to the nearest district health authority. In 1993, a Disease Control Division was created in the Public Health Department of the MOH which included an AIDS/STD (sexually transmitted diseases) section. Consultation and collaboration on HIV/AIDS are also maintained with international organizations such as WHO, United Nations Population Fund (UNFPA), United Nations Children's Fund (UNICEF), United Nations Development Programme (UNDP), and UNAIDS. The government has recognized the NGOs in HIV prevention and has, since 2002, allocated RM4 million annually for 10 years to the Malaysian AIDS Council (MAC).

AIDS SECTION 1993

POLICIES

POA 1988

POA 1998

NSP 06-10

NSP 11-15

National policies

The objectives of the national AIDS programme in Malaysia are consistent with WHO's Global Programme on AIDS, namely: (i) to prevent HIV transmission and to control its spread; (ii) to reduce the morbidity and suffering associated with HIV infection; (iii) to mobilize national resources within the government and non-government sectors to achieve the above objectives; and (iv) to promote international collaboration and cooperation among the nations of the world to prevent and control AIDS.

The MOH works with other ministries in the fight against HIV/AIDS through the National Committee on AIDS and the National Strategic Plan. Inter-agency and intersectoral collaboration is emphasized in recognition of the fact that AIDS is not just a health issue. Relevant ministries are represented in various programmes. For example, the AIDS education programme in schools is a joint collaboration between the MOH and the Ministry of Education. The Ministry of Information supports the MOH in the dissemination of information and health education messages on AIDS through the radio, television, and mobile information units.

Raising public awareness and knowledge on HIV/AIDS has been a focus of the MOH since it formulated its Plan of Action in 1988. In collaboration with the Department of Religious Affairs, MAC, and UNDP, the MOH has been seeking the involvement of religious leaders, and their participation in joint efforts to educate and to initiate or support community programmes related to HIV/AIDS (Box 6.2). Other targeted interventions are carried out by relevant NGOs and international organizations.

PLAN OF ACTION ON AIDS

POA 1998

- Blood safety
- Care and support
- Communications programming
- Counselling
- Drugs and alcohol
- Health education
- HIV and AIDS
- HIV in the workplace/World of work
- Human rights and ethics
- Injecting drug use
- Parent-to-child transmission
- People infected or affected by HIV or AIDS
- Prevention
- Research
- Resource mobilisation
- Sex workers and clients
- Sexually transmitted infection
- Stigma and discrimination
- Strategic planning and management
- Testing, notification and reporting

PARTICIPATIONS

- Public Health care provider
- Non Health Sectors
- Private Health care
- Non Government Organizations
- Religious Leaders
- Community
- PLHIV
- Individuals

National Strategic Plan

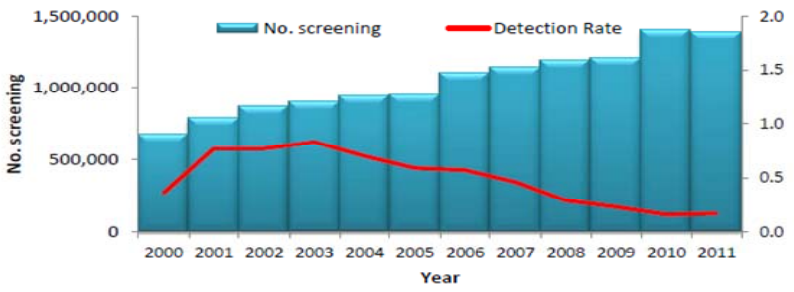
NSP 2006 -10

1. **Strengthening Leadership and Advocacy**
2. **Training and Capacity Enhancement**
3. **Reducing HIV vulnerability among Injecting Drug Users (IDUs) and their Partners**
4. **Reducing HIV vulnerability among Women, Young people and Children**
5. **Reducing HIV vulnerability among marginalized and vulnerable groups**
6. **Improving Access to Prevention, Treatment, Care and Support**

Current Activities

Healthy Individuals		Risk factor & Early Disease	Established Disease	Complication	
Health Promotion	Specific protection	Screening	Early Detection & appropriate treatment	Disability limitation	Rehabilitation
Primary Prevention		Secondary Prevention		Tertiary Prevention	
Surveillance Media campaign PROSTAR Counseling Healthy lifestyle HIV Screenings Health Education School program		Surveillance HIV Screenings Counseling Harm Reduction PMTCT Behaviour change STI TB	Surveillance HIV Screenings Counseling ARV therapy Treatment OI Support	Surveillance Counseling ARV therapy Treatment OI Support Care	

HIV Screening in Malaysia



COMPONENT OF HARM REDUCTION (IDU)

1. Methadone Maintenance Therapy (MMT)

2. Needle Syringe Exchange Program (NSEP)

- ARV Rx.
- STD Rx.
- HEALTH & MEDICAL CARE
- SOCIAL WELFARE
- VCT
- COUNCELING
- DRUG REHAB
- JOB PLACEMENT

Key Stakeholders Harm Reduction in Malaysia

NATIONAL

Ministry of Health Malaysia **(MOH)**
State Health Department & District Health Office,
Legal advisory
Universities
Private Practitioners
Royal Malaysian Police **(PDRM)**
National Anti Drug Agency **(AADK)**
Department of Islamic Development Malaysia (**JAKIM**)
Malaysia Prison Department
Malaysian AIDS Council **(MAC)**

MEMBERS OF NATIONAL TASK FORCE ON HARM REDUCTION

State : Harm Reduction Committee
Chairman : State Health Director
MoH / MAC / NADA / Police Force / State Religious (Islamic) Dept) / NGOS / Prison Dept/PLWHAs /

District : Harm Reduction Committee
Chairman : District Health Officer
MoH / MAC / NADA / Police Force /State Religious (Islamic) Dept) / NGOS / Prison Dept/PLWHAs

NEEDLES & SYRINGE EXCHANGE PROGRAM (NSEP)

- 3rd. June 2005: MoH announced that we will embark on NSEP and condom use to halt HIV among IDUs
- Piloted in February 2006 and ran by NGO
- 2008 : Initiation of NSEP in public health clinic



Methadone Maintenance Therapy (MMT)

- Using methadone (liquid) as substitution for heroine dan morphine
- Piloted in October 2005 at 10 facilities
- Carried out at government hospital and clinic, private clinic, facilities under National Anti Drug Agency and prison

GOOD PRACTICES IN ASIA

Effective paradigm shifts towards an improved national response to drugs and HIV/AIDS

SCALE-UP OF HARM REDUCTION IN MALAYSIA

World Health Organization Western Pacific Region

Ministry of Health Malaysia

WORLD HEALTH ORGANIZATION, WESTERN PACIFIC REGIONAL OFFICE AND WORLD HEALTH ORGANIZATION OFFICE OF THE REPRESENTATIVE FOR BRUNEI DARUSSALAM, MALAYSIA AND SINGAPORE

COVERED (up to 2011)

MOH PROGRAMME:
(REGISTERED CLIENTS)
- NSEP (34,244) – 221(NGO), 76 (MOH)
- MMT (20,955) - 218(MOH),

PRIVATE GPs (406)
- DST (23,473)

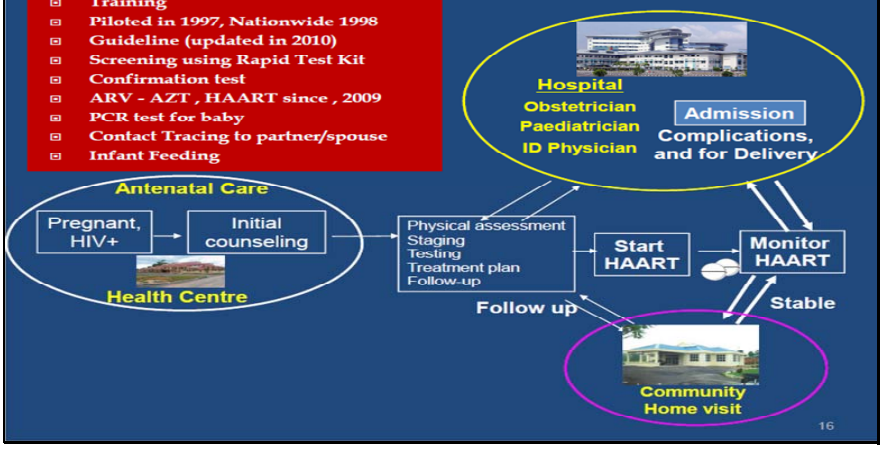
Risk factor	1990	2000	2011
Injecting drug use	470 (60.4%)	3,815 (74.7%)	1,348 (38.7%)
Sexual transmission	41 (5.2%)	964 (18.8%)	1,931 (55.5%)
Heterosexual	38 (4.8%)	902 (17.6%)	1,573 (45.2%)
Homosexual	3 (0.4%)	62 (1.2%)	358 (10.3%)

Source: Ministry of Health (2011)

eMTCT IN MALAYSIA

MTCT <5%, or MTCT<2% in non-breastfeeding populations

- Training
- Piloted in 1997, Nationwide 1998
- Guideline (updated in 2010)
- Screening using Rapid Test Kit
- Confirmation test
- ARV - AZT , HAART since , 2009
- PCR test for baby
- Contact Tracing to partner/spouse
- Infant Feeding



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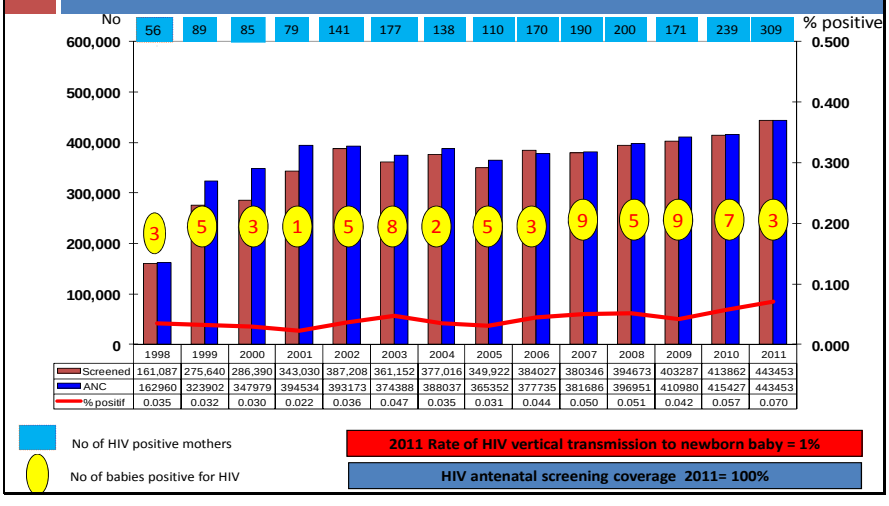
ANTENATAL HIV SCREENING (MOH)1998 - 2011



	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Screened	161,087	275,640	286,390	343,030	387,208	361,152	377,016	349,922	384027	380346	394673	403287	413862	443453
ANC	162960	323902	347979	394534	393173	374388	388037	365352	377735	381686	396951	410980	415427	443453
% positif	0.035	0.032	0.030	0.022	0.036	0.047	0.035	0.031	0.044	0.050	0.051	0.042	0.057	0.070

No of HIV positive mothers

No of babies positive for HIV

2011 Rate of HIV vertical transmission to newborn baby = 1%

HIV antenatal screening coverage 2011= 100%

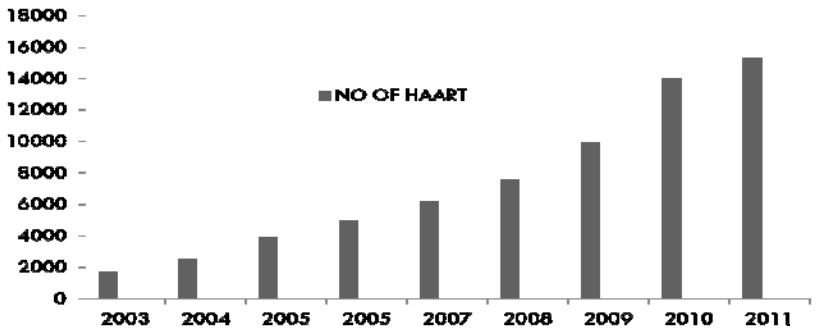
STRATEGIES PMTCT

- Services at Private Clinics / Hospitals
- Close monitoring of positive cases
- Miss opportunity – labour rooms
- Quality assurance

Enhanced towards

ELIMINATION BY 2015

CUMMULATIVE ON HAART AS 31 DEC 2011



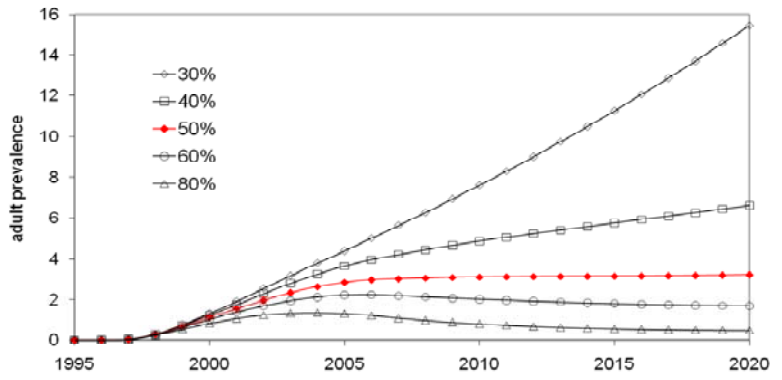
520 PAEDIATRIC CASES ON HAART BY END 2011

Next :

National Strategic Plan On AIDS 2011 - 2015

Reaching 80% MARPs coverage

28



July 20, 2012 UNAIDS

Prioritization of resources to avert the most new infections

	Cost of Interventions	
Effect (averting new infections)	**Low-cost, High-impact** (prevention among most-at-risk populations)	**High-cost, High-impact** (antiretroviral treatment and prevention of mother-to-child transmission)
	Low-cost, Low-impact (general awareness programmes through mass media and other channels)	**High-cost, Low-impact** (health systems strengthening through universal precautions and injection safety)

Source: Report of the Commission on AIDS in Asia

July 20, 2012

High impact should be the main guiding factor for choosing programs for funding and this will be determined on how effective they are in preventing new infections and improving quality of life for those living with the virus. Low impact programs are generally attractive because they are soft and easy to implement, but they have minimal impact in reducing new infections.

Early action in HIV prevention can:

Save money: $1 in prevention saves $8 in future treatment costs

Avert large-scale epidemics

Focused intervention for 5% population can avert large scale epidemic

Free up development resources

Normative costs in:

- Early phase: $0.30 per capita
- Expanding phase: $1 per capita
- Maturing phase: $2.50 per capita

STRATEGIES

- **Strategy 1:** **Improving the quality and coverage of prevention programmes among most at risk and vulnerable populations**
  - 1.1 Prevention of HIV transmission through the sharing of needles and syringes
  - 1.2 Prevention of HIV transmission through unprotected sex
  - 1.3 Prevention of parent to child transmission (PPTCT)
- **Strategy 2:** **Improving the quality and coverage of testing and treatment.**
- **Strategy 3:** **Increasing the access and availability of care, support and social impact mitigation programmes for People Living with HIV and those affected.**
- **Strategy 4:** **Maintaining and improving an enabling environment for HIV prevention, treatment, care and support.**
- **Strategy 5:** **Increasing the availability and quality of strategic information and its use by policy makers and programme planners through monitoring, evaluation and research.**

GOAL **aims to prevent and reduce the risk and spread of HIV infection, improve the quality of life of People Living with HIV, and reduce the social and economic impact resulting from HIV and AIDS on the individual, family and society**

SPECIFIC OBJECTIVES

1. Reduce by **50% the number of new HIV infections** by scaling up, improving upon and initiating new and current targeted and evidence based comprehensive prevention interventions
2. **Increase coverage and quality of care, treatment and support for** People Living with HIV and those affected
3. **Alleviate the socioeconomic and human impact of AIDS** on the individual, family, community and society.
4. **Create and maintain a conducive and enabling environment for government and civil society** to play meaningful and active roles in decreasing stigma and discrimination.
5. **Further increase general awareness and knowledge of HIV, and reduce risk** behaviour for **at risk and vulnerable populations.**

STRATEGIC TARGETS

1. Comprehensive HIV prevention programmes are able to effectively cover 80% of most at risk populations.
2. 60% of most at risk populations use condoms consistently.
3. 60% of MARPs who are IDUs use clean injecting equipment.
4. All cases of vertical HIV transmission are able to be prevented with all HIV positive pregnant mothers receiving treatment and children born receive ARV prophylaxis
5. Provision and access to comprehensive services for at least 80% of People Living with HIV who are eligible for ARV treatment, care and support which are non-discriminatory and professional.

Key achievements

- **PMTCT**
  - All public facilities implement ANC HIV Screening
  - HIV Screening reached 99.8% & ARV to mothers reached 100%
- **Harm Reduction**
  - Aim to reach 40% IDUs in 2010 and 80% in 2015
  - Needle Syringe Exchange and Methadone Maintenance therapy
- **ARV therapy**
  - All facilities (Hospital & Health Centres) able to provide HAART
  - Providing HAART in prison and Drug Rehabilitation Centres
- **HIV Screening**
  - All public facilities able to do HIV screening
- **HIV Education**
  - 3 days module for National Service Trainers (120,000 annually)
  - 3 Module on Islam and HIV for religious leaders and Imam

Lessons learnt

- Strong leadership needed in implementing interventions
- Smart Partnership (Government, Non-government, Private and Communities) is important in scaling-up programmes
- Good surveillance data important in drafting policy
- Monitoring and Evaluation must be in place for any interventions
- Workable Strategic Plan and Setting target are important in implementing prevention, treatment, care and support for HIV/AIDS