

HIV Epidemic in Asia

Implications for HIV vaccine efficacy trials

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International
Vaccine
Institute

Outlines

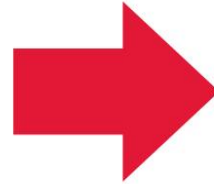
- HIV prevention and HIV vaccines
- RV144 next steps
- HIV epidemiological data in Asia
- HIV vaccines for Asia
- Asia country-specific data in MSM
- Conclusions

Toward Ending the HIV/AIDS Pandemic

**Non-vaccine
prevention
modalities**

+

**An effective
HIV vaccine**



**AIDS-Free
Generation**

What have learned?

- **Proven methods of partially effective prevention**
 - Medical male circumcision
 - Pre-exposure prophylaxis (PrEP)
 - Treatment as Prevention
- **HIV therapy is amazingly effective**
 - Adherence is essential
 - All HIV positive people should be offered therapy as soon as diagnosed
- **New advances in prevention and treatment are needed to help end the epidemic**
- **To make further progress we must integrate biomedical with behavioral and social science research**

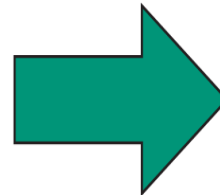
Promise and pitfalls of PrEP

- PrEP, as defined as a daily pill containing FTC/TDF, is the U.S. FDA approved biomedical prevention modality PrEP
- PrEP is amazingly effective, **IF** the PrEP user adheres
- PrEP is not a magic bullet, must be delivered in the context of comprehensive prevention packages
- Need to address the access and adherence issues
- Next generation of PrEP agents beginning evaluation
 - Injectable (may circumvent issues linked to adherence)
 - Long-acting, easier to use, safer, more accessible due to lower cost

Towards an HIV Vaccine

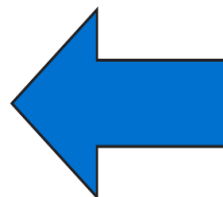
Empirical or Inductive Approach:

Test promising candidates until protection achieved, identify correlates and optimize regimen



Effective Vaccine

Effective Vaccine



Theoretical or Deductive Approach:

Determine optimal immune correlate of protection, design immunogen to induce immune correlate

HIV-1 Vaccine Efficacy Trials

Vaccine regimen	Location/risk population	Overall vaccine efficacy	Increased risk of infection	Immune correlates of decreased vaccine efficacy ^a	Immune correlates of decreased HIV risk	Immune correlates of immune control post infection	Virus sieve	Host genetic correlates
VAX003 (Phase III) Protein/ Alum (CRF01_AE/Clade B Env) ⁵²	Thailand/injection drug users	No efficacy	No	No	No ⁵²	No	No ^{118,b}	n/d
VAX004 (Phase III) Protein/ Alum (Clade B Envs) ⁵³	USA/MSM/high risk women	No efficacy	No	No	Yes ADCVI, CD4 Blocking, Tier 1 NAb	n/d	No ^{160,161}	Yes Fcγ receptor IIIa genotype (VV genotype) ¹²⁵
STEP HVTN502 (Phase IIb) Ad5 Vector (Clade B Gag/Pol Nef) ⁵⁴	North/South America, Australia, Caribbean/MSM and High Risk Heterosexual Men and Women	No efficacy ^c	Yes	n/d	No	Yes T cell breadth/ magnitude, Lower VL	Yes ⁶⁷	Yes HLA alleles (B*27, B*57, B*58:01), Lower viral load
Phambili HVTN503 (Phase IIb) Ad5 Vector (Clade B Gag/Pol Nef) ⁵⁷	South Africa/Hetero-sexual Men and Women	No efficacy ^d	n/d	n/d	n/d	n/d	n/d	n/d
RV144 (Phase III) ALVAC vector (Clade B Gag/Pro + CRF01_A/E Env) + Protein/ Alum (CRF01_AE/B Env) ⁵⁰	Thailand/Community	31% efficacy	No	Yes Plasma Env IgA ^{71,74}	Yes V1V2 IgG, Linear V2, V1V2 IgG3, Interactions (ADCC, Avidity, Tier 1 NAb, IgA), CD4 ⁺ T cell Polyfunction, Cytokines ^{71-73,75,111}	n/d	Yes ^{85,162}	Yes HLA A*02 allele ¹²⁶ ; FcγRIIC -118 L allele ¹¹⁴ ; DQB1*06 ¹¹³
HVTN505 (Phase IIb) DNA/ Ad5 (Clade A, B, C Env, Clade BGag/Pol) ⁶⁰	USA/MSM and TG, Ad5 seronegative, Circumcised	No efficacy ^c	No	No	Yes CD8 ⁺ Env T-cell Polyfunction ^e	n/d	Yes ⁶⁶	n/d

First Signal of Efficacy (31%) in an HIV Vaccine Clinical Trial – RV144



The
New England
Journal of Medicine

Established in 1812 as THE NEW ENGLAND JOURNAL OF MEDICINE AND SURGERY

Volume 361

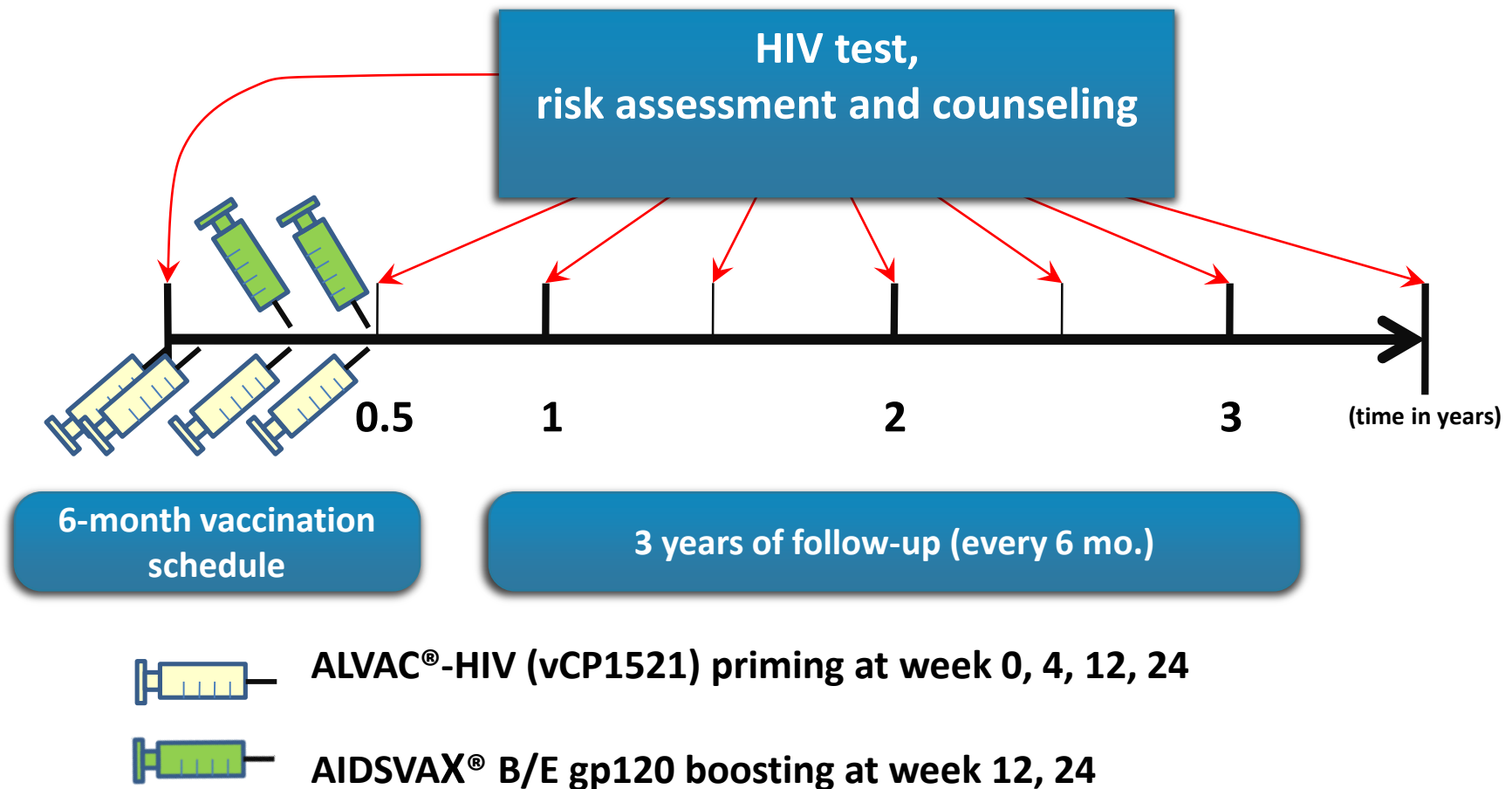
December 3, 2009

Number 23

Vaccination with ALVAC and AIDSVAX to Prevent HIV-1 Infection in Thailand

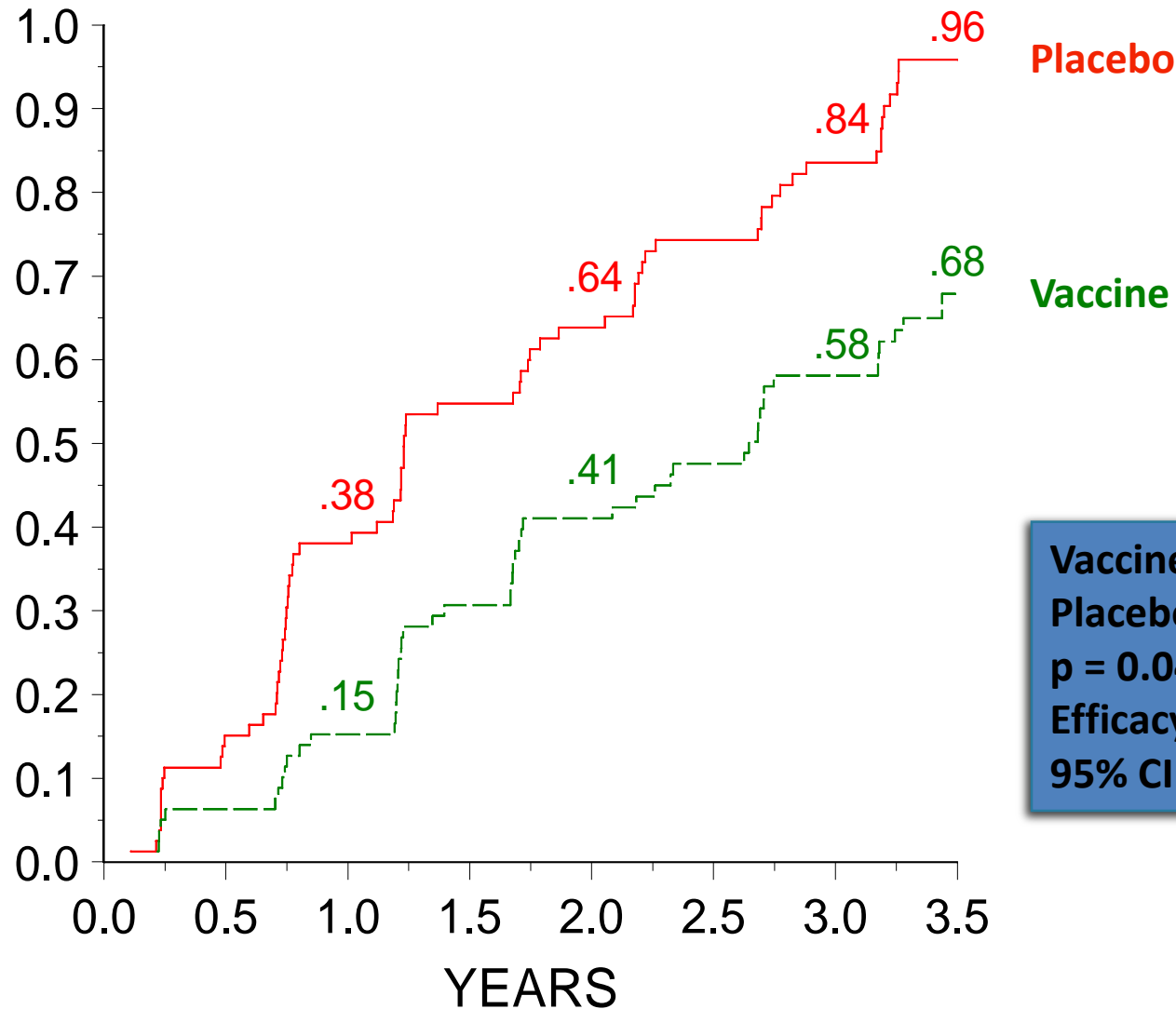
**S Rerks-Ngarm, JH Kim, NL Michael, et al. for the
MOPH-TAVEG Investigators**

RV144 Vaccination and Follow-up Schedule



RV144

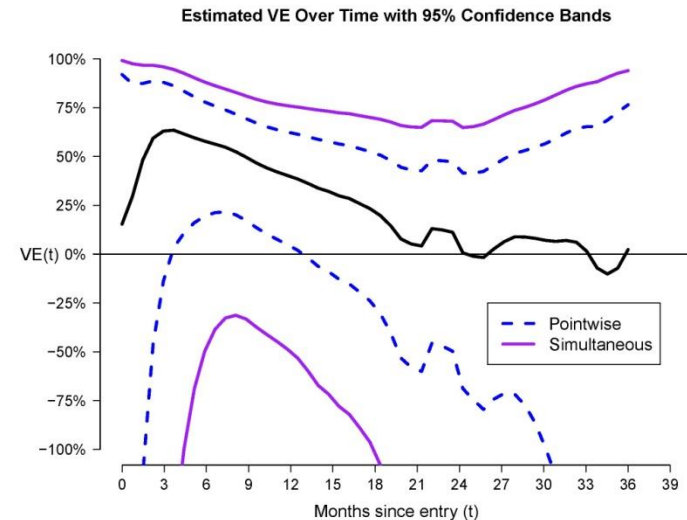
Acquisition Endpoint: Modified Intent-to-Treat (mITT)



Vaccine infections: 51
Placebo infections: 74
 $p = 0.04$
Efficacy: 31.2%
95% CI (OBF): 1.1, 51.2

Thai Phase III HIV Vaccine Trial (RV144) Summary

Early (VE = 60%) effect wanes
(Robb et al, Lancet ID 2012)



bAb decreases rapidly
Rerks-Ngarm et al, NEJM, 2009.

Antigen	Reciprocal GMT (Range)	
	2 weeks	24 weeks
B gp120	31207 (800-204800) (99% responders)	1758 (200-25600)* (99% responders)
E gp120	14558 (200-204800) (99% responders)	1000 (100-12800)* (99% responders)
B p24	205 (100-1600) (52% responders)	149 (100-200)* (18% responders)

P<0.0001 compared to placebo group - all Antigens

*: P<0.001 compared to 2 week time-point

Dr. Mark de Souza



Immune Correlates Analysis from RV144



Immune-Correlates Analysis of an HIV-1 Vaccine Efficacy Trial

BF Haynes, PB Gilbert, MJ McElrath, et al.

- **IgG antibodies against the V1V2 region of the HIV-1 envelope protein associated with reduced infection**
- **Non-neutralizing antibodies mediate ADCC activity**
- **IgA antibodies correlated with increased infection**

Immune Correlates of HIV Risk in RV144

V2 Correlate

V1V2 IgG, V1V2 IgG Breadth, V2 Linear AE hotspot
V1V2 IgG3

Structure Function of V2 Mabs and Sieve Analysis

(Haynes *et al.* NEJM 2012; Liao *et al.* Immunity 2012; Gottardo *et al.* Plos One 2013; Zolla-Pazner *et al.* Plos One 2014; Yates, Tomaras *et al.* Sci. Trans. Med 2014; Chung *et al.* Cell 2015)

T Cell Correlate

Cytokine response (IL-10, IL-13) from
Env stimulated PBMC

Polyfunctional CD4+ T cell (CD40L, IL-2, IL-4, IFN- γ and TNF- α) and (CD40L, IL-2 and IL-4)

(Haynes *et al.* NEJM 2012;
Lin *et al.* Nature Biotechnology 2015)

Host Genetics and Antibodies

IgG, IgG3, nAb, Avidity and Fc γ RIIC SNP

IgA/ HLA A*02 allele

IgA/ HLA II DQB1*06

IgG/ HLA II DPB1*13

(Li *et al.* JCI 2014; Gartland *et al.* JV 2014;
Prentice *et al.* Sci. Trans. Med. 2015)

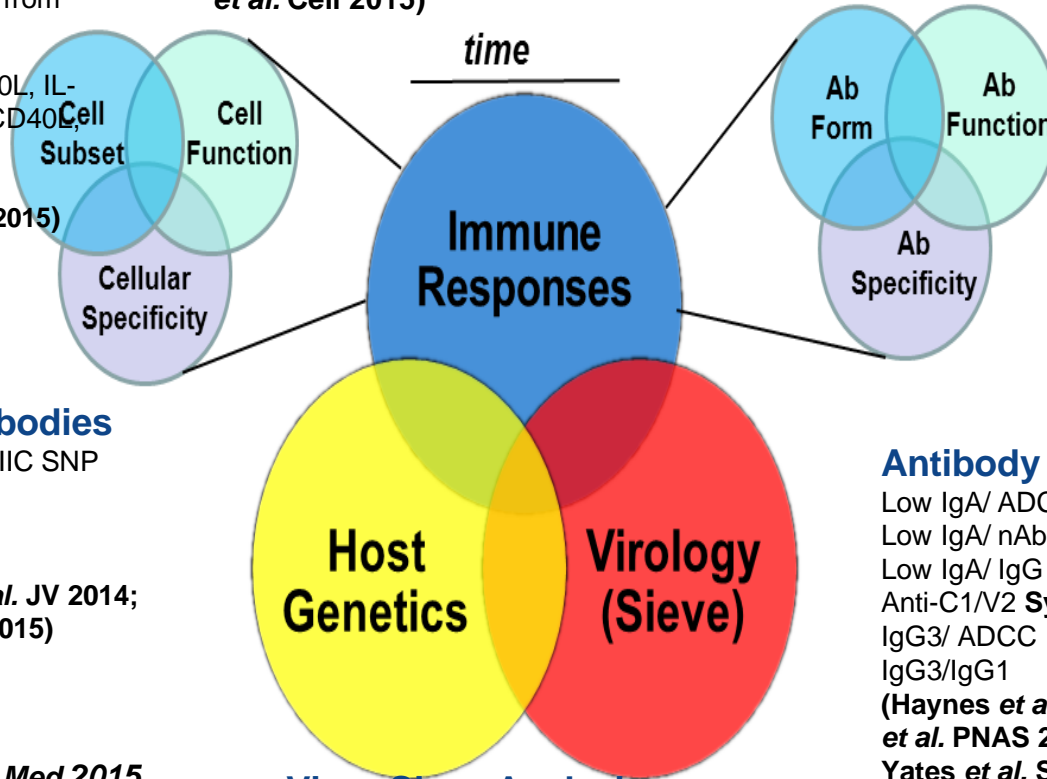
Kim, Excler, Michael *Annu Rev Med* 2015
Tomaras, Haynes *Vaccines* 2014, 2(1), 15-35.
Tomaras, Plotkin *Immunological Reviews* 2017, 275:245-261

Virus Sieve Analysis

V2 Sieve (and V2 mAbs dependent on 169K)

Genetic distance from Vaccine strain /IgG and IgG3 V1V2 correlates

(Rolland *et al.* Nature 2012; Liao *et al.* Immunity 2012; Gilbert *et al.* Statistics in Biosciences 2016)



IgA Correlate

IgA Env Score
IgA A. OOMSA gp140 CF
IgA. A1 Congp140
IgA C1
IgA Non-Vaccine Strains
IgA/IgG ratio

(Haynes *et al.* NEJM 2012;
Tomaras, Ferrari *et al.* PNAS 2013)

Antibody Interactions

Low IgA/ ADCC (Blocking ADCC)

Low IgA/ nAb

Low IgA/ IgG Env Avidity

Anti-C1/V2 Synergy

IgG3/ ADCC

IgG3/IgG1

(Haynes *et al.* NEJM 2012; Tomaras, Ferrari *et al.* PNAS 2013; Pollara *et al.* JVI 2014;
Yates *et al.* Sci. Trans. Med 2014; Chung *et al.* Cell 2015)

Strategies to amplify RV144 responses

MORE, BETTER, LONGER

- Strength
- Breadth
- Durability

HOW

- New proteins
- Potent adjuvants
- Additional boosts
- Longer intervals
- New vectors

Post RV144 Steps – Learn more, improve

- RV305 – late boost of RV144 vaccine recipients
- RV305a – Additional boosts
- RV306 – RV144 regimen with boosts at different intervals
- **RV306a** – Additional boosts with different proteins
- RV328 – AIDSVAX BE only
- **RV509** – RV144 regimen with new proteins and additional boosts

South Africa Strategy

- The RV144 regimen tested in South Africa showed same safety and immunogenicity patterns (HVTN 100)
- A similar prime-boost regimen using ALVAC-HIV and gp120 subtype C formulated with MF59 (HVTN 107)
 - South Africa
 - Lower V1V2 antibody response than in RV144
 - Limited cross-reaction with other HIV-1 subtypes
- The subtype C regimen has now entered a Phase IIb trial (HVTN 702) in South Africa in heterosexual populations. However, a fraction of this population appears to also practice anal intercourse, a possible confounding factor for efficacy.

Epidemiological Patterns of HIV Infection

Africa

- Mostly **heterosexual** transmission
- Unveiled and expanding MSM transmission
- **Mother-to-child transmission**

Asia

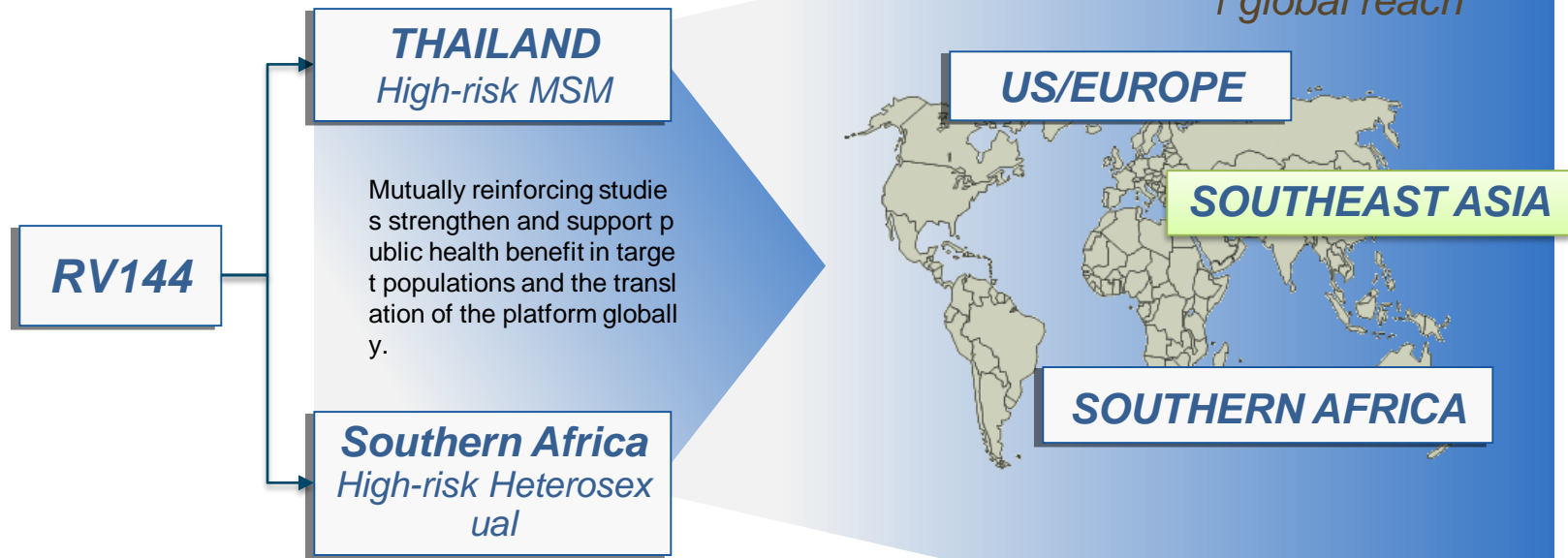
- Heterosexual
- Mostly **MSM**, expanding
- IDU, decreasing

Public Health Impact and Regional Relevance

*Precedent for
vaccine efficacy*

*Focus on regional
public health impact*

*Future amplification of
global reach*



Regional Strategy for Asia

- The initial follow-up clinical development strategy with the RV144 regimen was to conduct a Phase IIb in men having sex with men (MSM) in Thailand. However, this strategy was hampered by the lack of agreement between pharma companies regarding manufacturing of AIDSVAX B/E and the failure to identify a suitable industrial partner.
- Clinical trial data suggest that that gp120 A244 Δ 11 (CRF01_AE component of AIDSVAX B/E) has special characteristics unmatched by other envelope proteins.
- This triggered a renewed interest of donors and Sanofi Pasteur in conducting a Phase IIb trial in MSM in Asia where HIV incidence remains high in several countries.

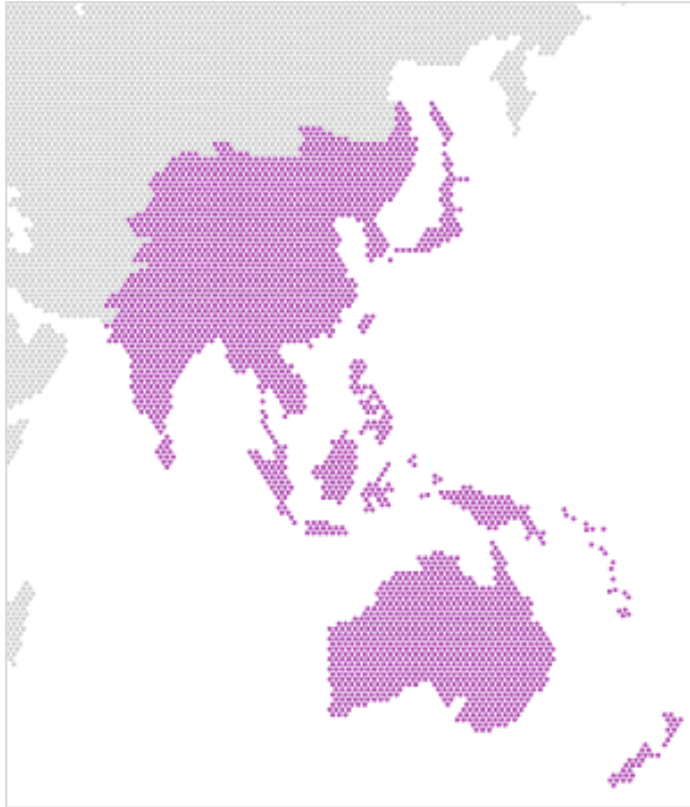
Clinical development pathway

- **RV509 bridging study**
 - US
 - Germany
 - Thailand
- **Efficacy trials**
 - B subtype: US and Europe
 - **AE: Asia**

GENERAL HIV EPIDEMIOLOGICAL PATTERNS IN ASIA



HIV and AIDS in Asia and the Pacific 2015



Asia & The Pacific (2015)

5.1 million people living with HIV

0.2% adult HIV prevalence

300,000 new HIV infections

180,000 AIDS-related deaths

64% know their status

41% adults on antiretroviral treatment

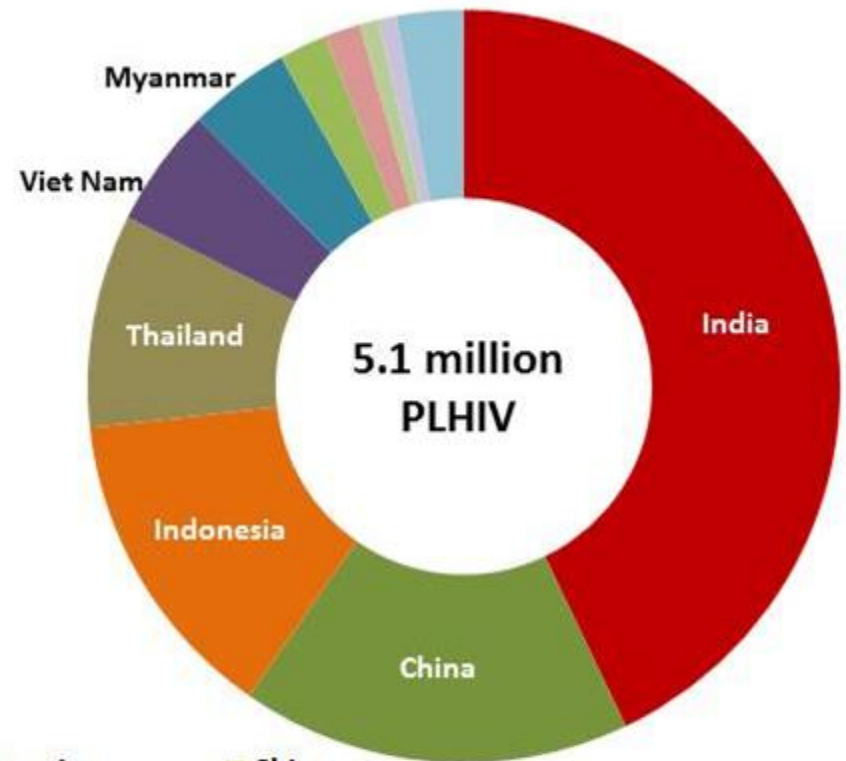
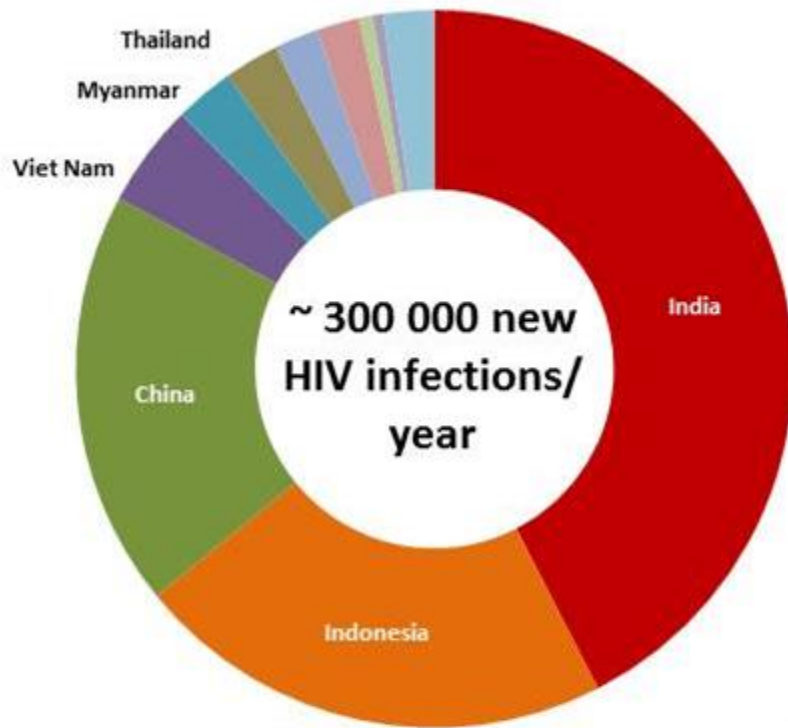
34% virally suppressed

Source: UNAIDS Gap Report 2016

General HIV epidemiological data in Asia 1

- In 2014, the Asia-Pacific region was home to more than a half of the world's population and 15.2% of the estimated 36.9 million people living with HIV globally. Most of the region's HIV-positive people (~90%) live in five countries - **China**, India, Indonesia, **Thailand and Vietnam**.
- Globally, HIV incidence decreased by 35% since 2000 and AIDS-related deaths dropped by 42% since 2004. New HIV infections declined in some countries in the region (India, Myanmar, Thailand, Cambodia, and Viet Nam) but increased in others (Pakistan, Philippines, and Indonesia).

The majority of estimated new HIV infections (on the left) and people living with HIV (on the right) are in India, **China**, Indonesia, **Thailand and Viet Nam**/ Myanmar. HIV is concentrated among key populations: MSM, TGW, FSW and PWID.



- | | | |
|---------------|-------------------|--------------------|
| ■ India | ■ Indonesia | ■ China |
| ■ Viet Nam | ■ Myanmar | ■ Thailand |
| ■ Philippines | ■ Malaysia | ■ Papua New Guinea |
| ■ Nepal | ■ Other countries | |

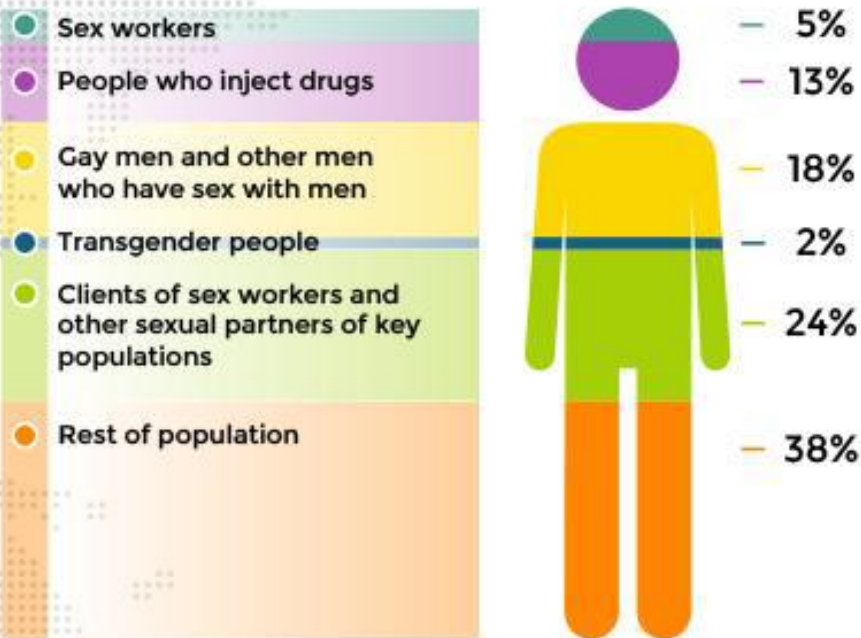
New HIV infections in key affected populations

DISTRIBUTION OF NEW HIV INFECTIONS AMONG POPULATION GROUPS BY REGION

2014

Source: UNAIDS
special analysis, 2016

Asia and Pacific

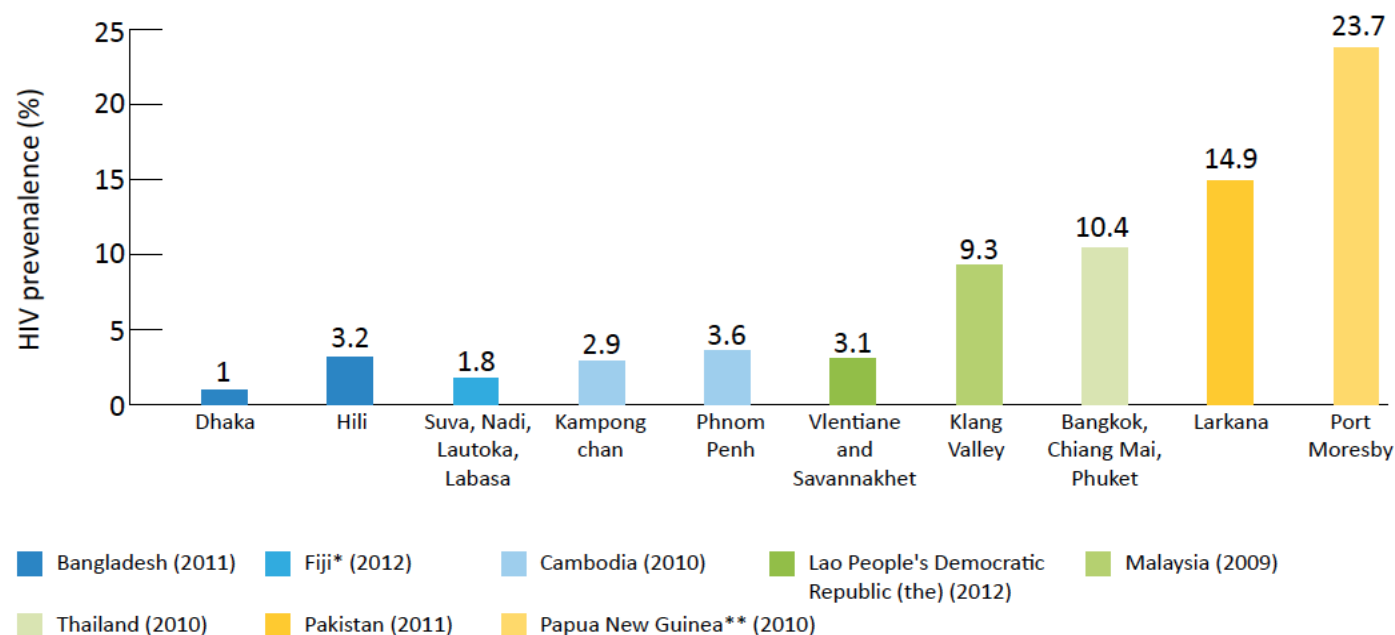


General HIV epidemiological data in Asia 2

- Epidemics in the region can be characterised as being **concentrated and growing in key populations, mainly among MSM, particularly young MSM, or shifting towards MSM as the main mode of transmission.**
- **HIV prevalence is 5-15 times higher among MSM** compared to the general population in South and South-East Asia. Infections among female sex workers (FSW) have slowed but remain important contributors to HIV transmission in the region.
- Limited data are available about the HIV epidemics in transgender people (TG), estimated to be 9–9.5 million in the region, and small-scale research is mostly limited to TG women who have sex with men. In several cities HIV prevalence in this group was substantially higher than in general population of reproductive age, and even higher than in MSM.

Transgender people in selected cities in Asia and Pacific

Figure 2: HIV prevalence among transgender people in select cities in Asia and the Pacific, 2009–2012



* Transgender sex workers

** Transgender sex workers, sample size = 38

Source: HIV and AIDS Data Hub for Asia Pacific (www.aidsdatahub.org), based on integrated bio-behavioural surveys reported in global AIDS response progress reports from 2012.

General HIV epidemiological data in Asia 3

- While disproportionately affected by HIV, the key risk populations are mostly underserved by HIV prevention programs.
- **Throughout Asia, less than 60% of MSM and FSW know where to get tested for HIV or have received condoms through distribution programs** (level of condom use > 80% is considered to have an impact on HIV epidemic). Condom promotion programs are not reaching men at a sufficiently high level: rates of condom use at last sex among MSM are half of the rate in FSW (two thirds among male sex workers (MSW)).
- Studies in MSM have provided evidence of the safety and efficacy of daily tenofovir, alone or in combination with emtricitabine for HIV pre-exposure prophylaxis (PrEP). No studies were conducted to evaluate PrEP efficacy specifically in TG people, but TG participants of the iPrEx trial were protected from HIV if they had taken PrEP.

“Only biomedical HIV prevention strategy in MSM, will be instrumental in achieving HIV epidemic control in this group.”

- No evidence for efficacy of treatment for prevention (TFP) in protecting MSM from HIV infection was found.
- The rationale for this approach is based on assumptions about biological plausibility and external validity of latency-based efficacy found in heterosexual couples. This is different from the route and timing of HIV transmission in MSM.
- New HIV infections in MSM principally occur in chains of acutely HIV-infected highly sexually active young men, in whom acquisition and transmission are correlated in space and time. By the time TFP renders its effects, most new HIV infections in MSM will have already occurred.
- Generally, HIV cascade data in MSM show a sobering picture of TFP in engaging and retaining MSM along the continuum.
- Widening the cascade with a preventive extension, including PrEP, the first proven efficacious and only biomedical HIV prevention strategy in MSM, will be instrumental in achieving HIV epidemic control in this group.

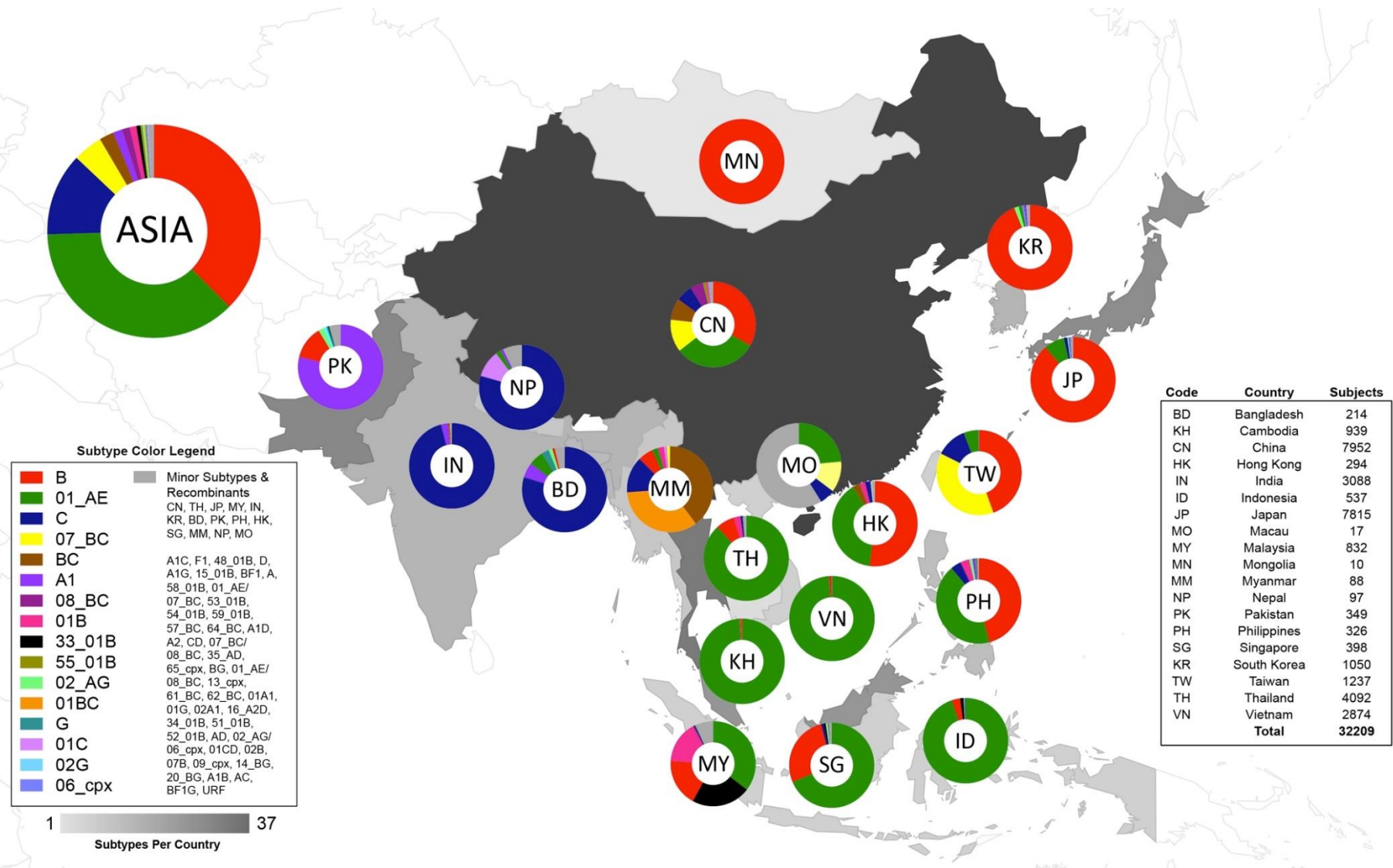
van Griensven F, et al. Sex Transm Infect 2017;93:356–362.

Zablotska I, et al. JIAS 2016, 19(Suppl 6):21119.

HIV-1 molecular epidemiology patterns

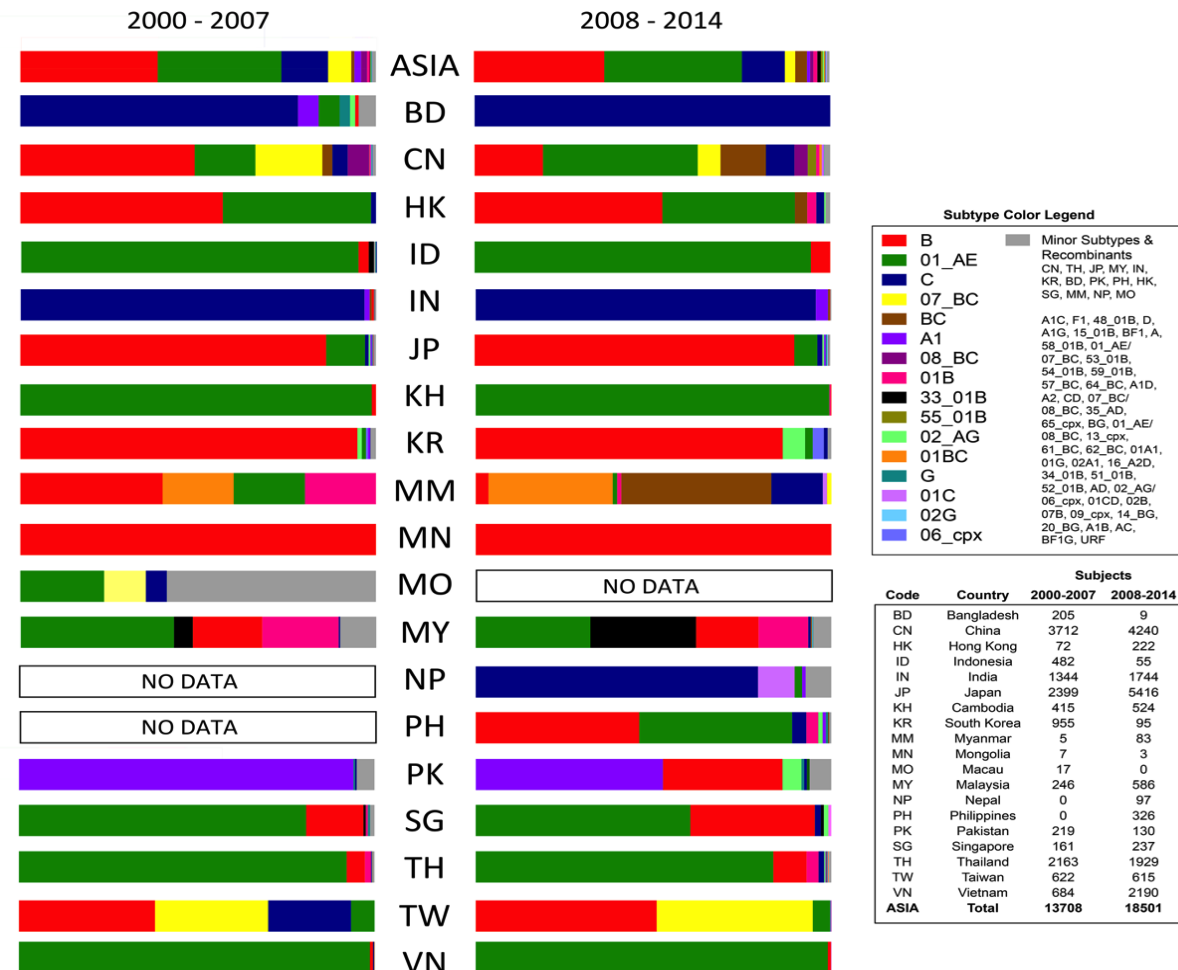
- CRF01_AE remains predominant in South East Asia with a growing presence in China and an increasing number of recombinant forms containing CRF01_AE, B and C subtypes. **CRF01_AE dominates** in Thailand, Cambodia, Indonesia, Laos, Myanmar, and Viet Nam.
- In Malaysia, co-circulation of CRF01_AE and subtype B has resulted in the emergence of CRF33_01B in approximately 20% of HIV-1 infected individuals, now also described in Indonesia.
- Co-circulation of CRF01_AE and subtype B in the Philippines
 - *Phanuphak et al. ARHR 2015*

HIV-1 molecular epidemiology in Asia (2000-2014)



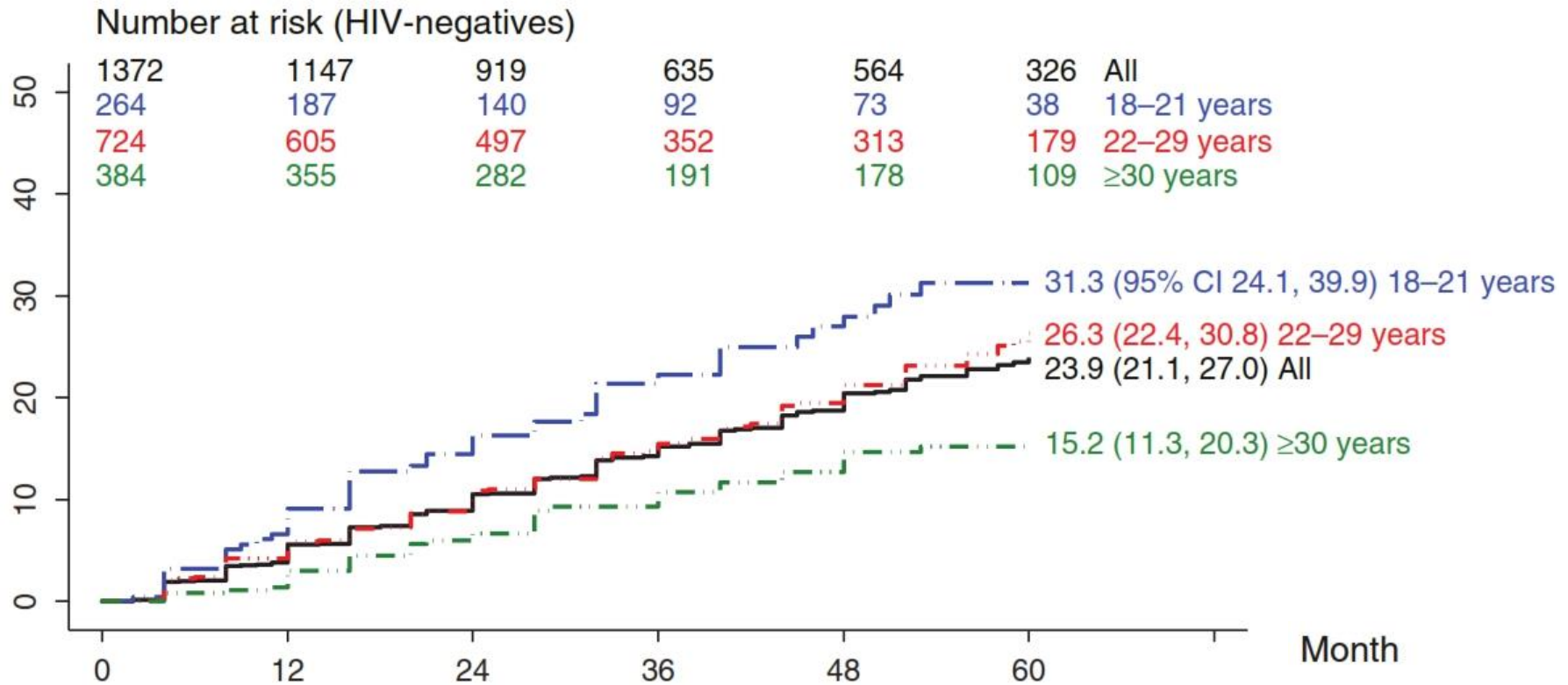
Geographical and temporal distribution of circulating HIV-1 subtypes by country: 2000-2007 and 2008-2014

Phanuphak et al.
ARHR 2015



THAILAND

“Explosive HIV epidemic”among MSM in Bangkok

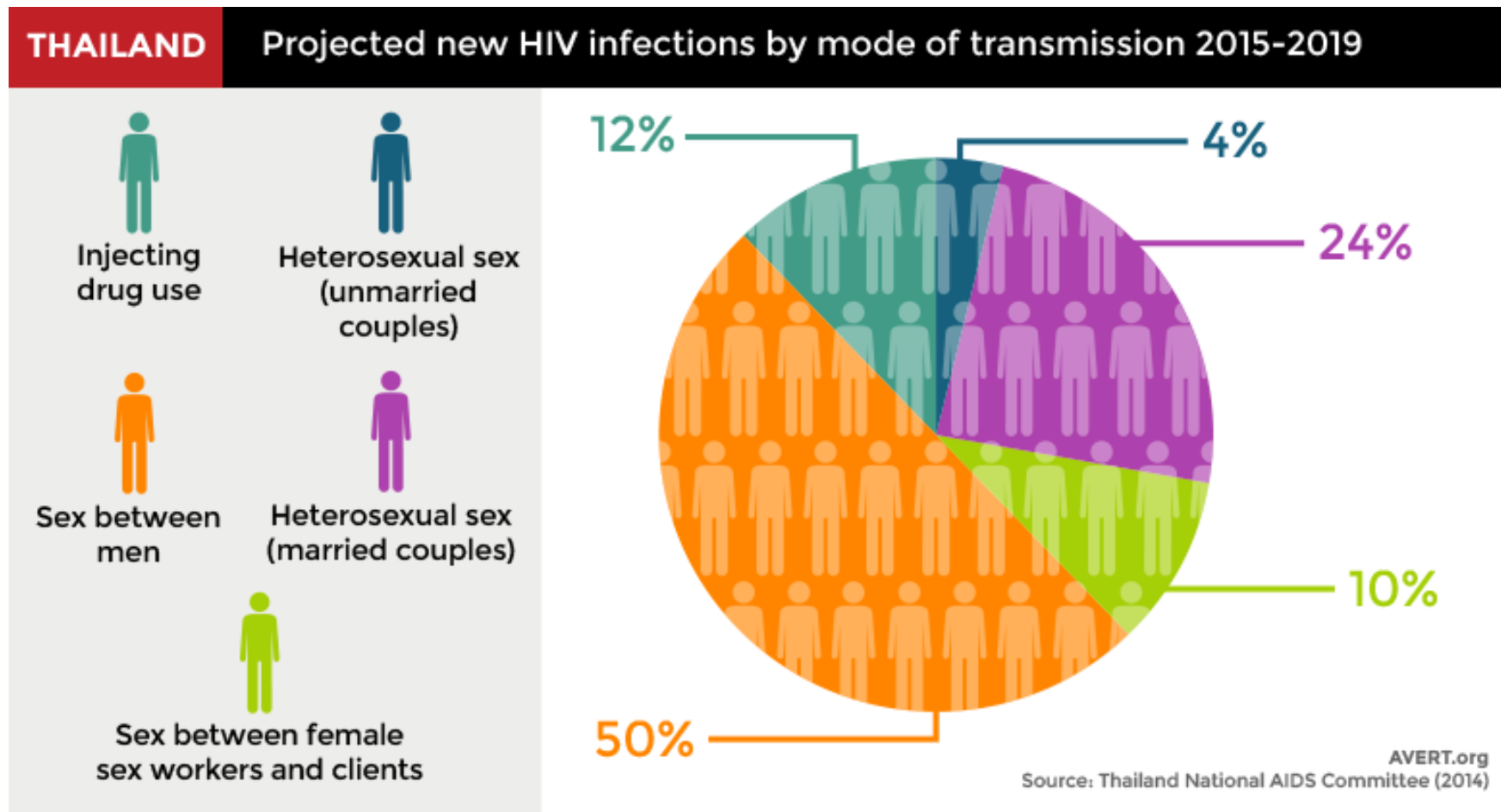


60-month cumulative HIV-incidence among MSM in Bangkok, 2006–2012.

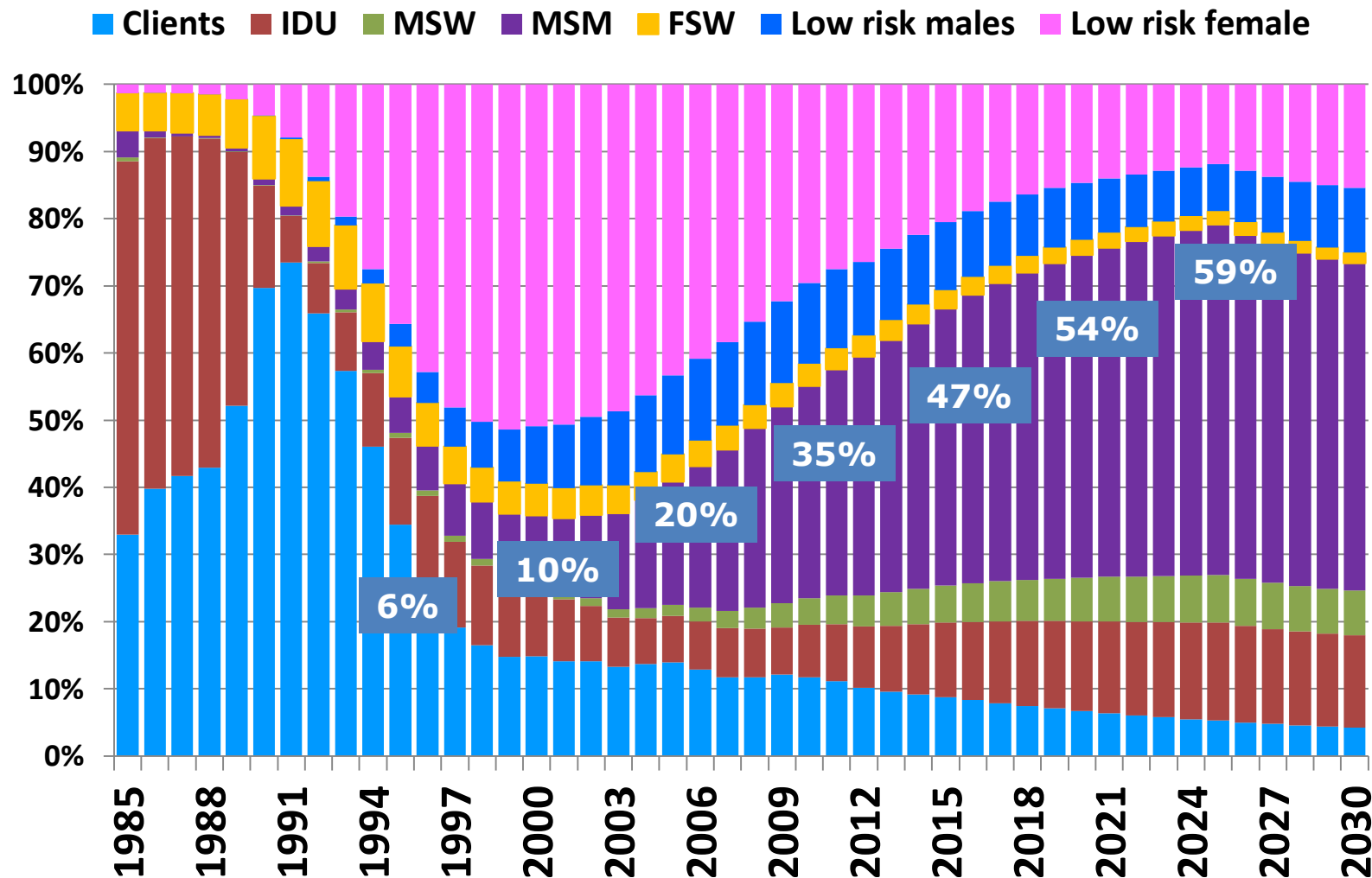
MSM=men who have sex with men

van Griensven F, et al. AIDS, 2013 Mar 13;27(5):825-32.

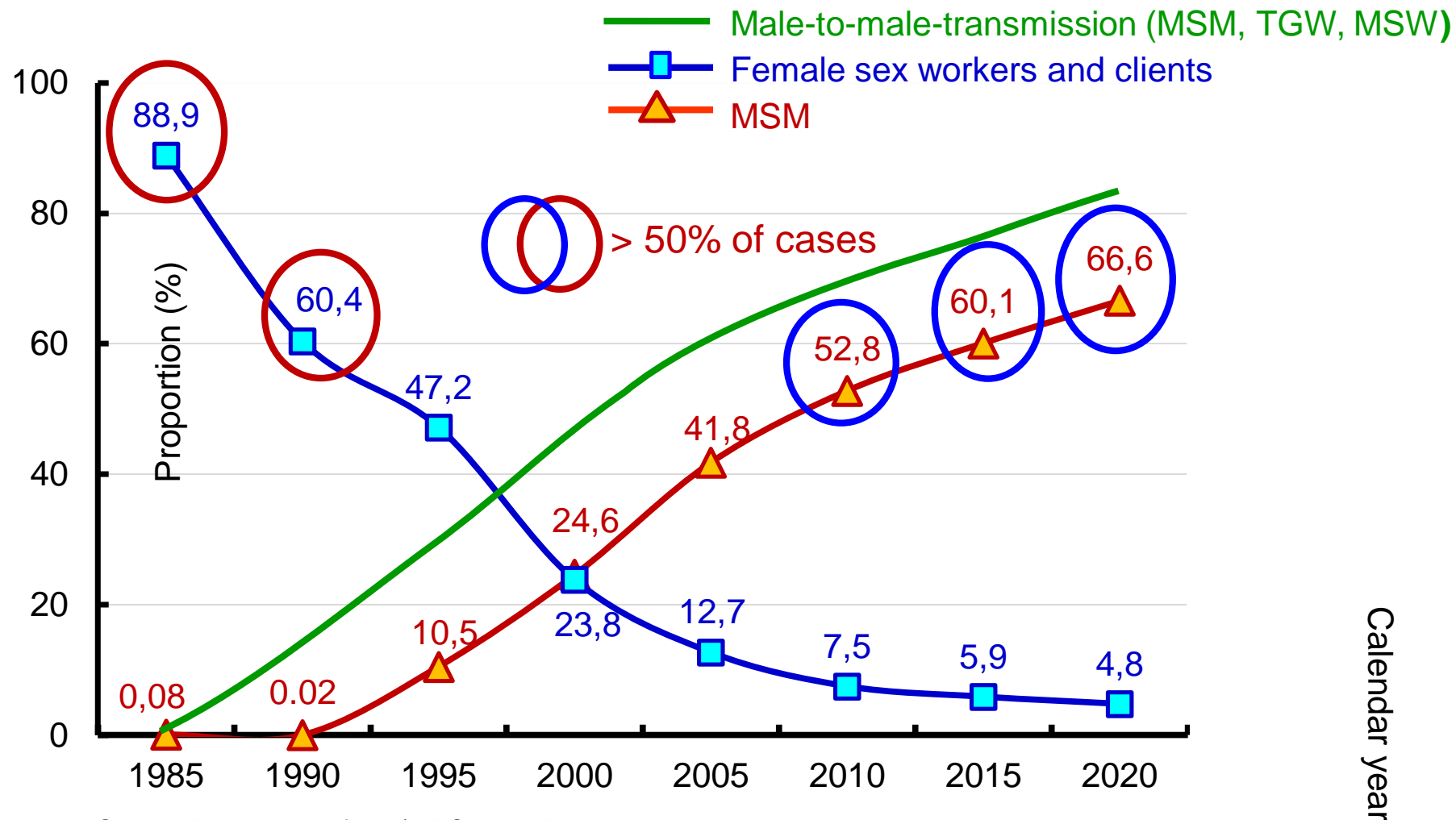
Projection of new HIV infections in Thailand 2015-2019



Increasing proportion of new HIV infections in Thailand from MSM over time



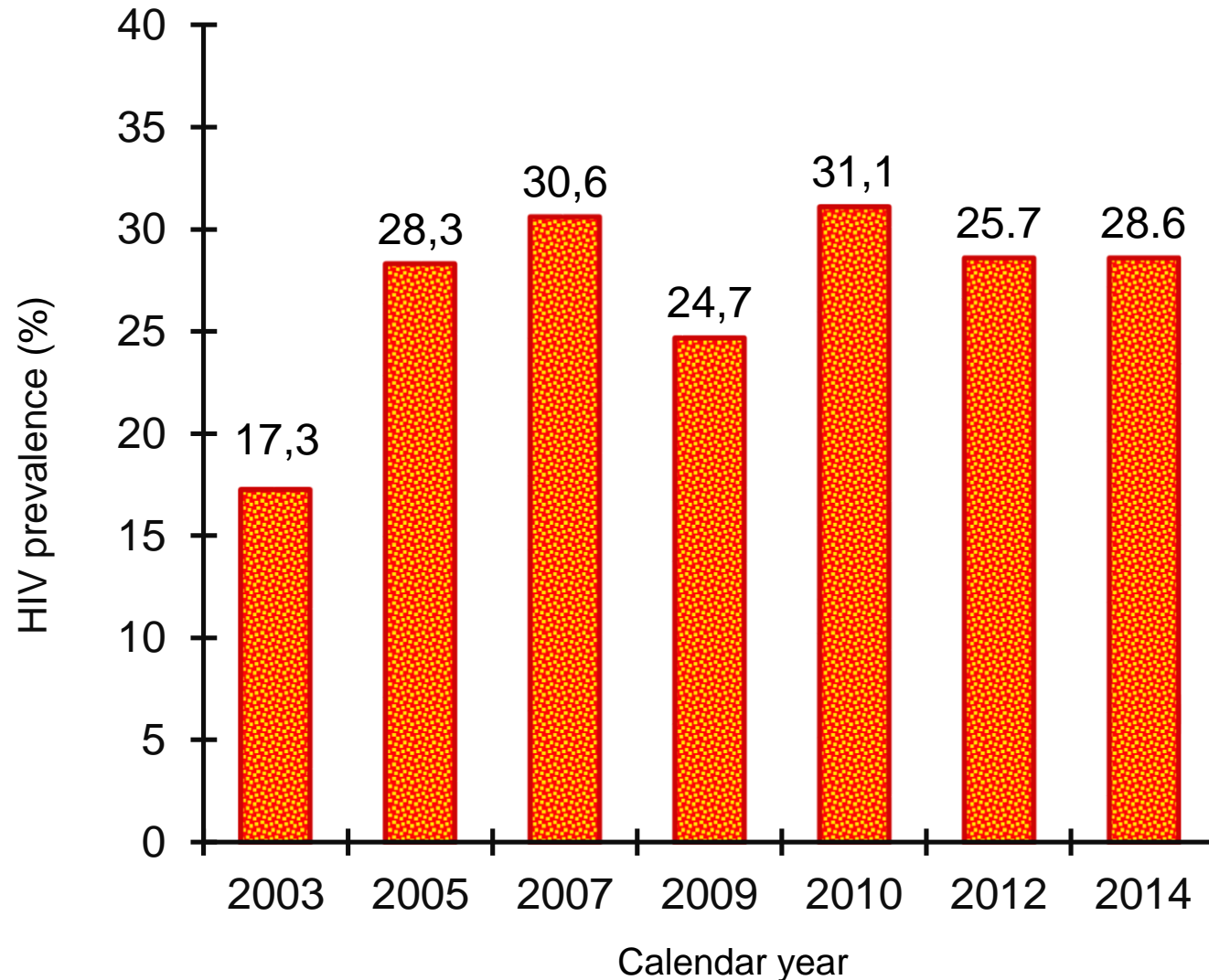
Estimated proportion of annual new HIV infections in MSM, from male-to-male sex and FSW and clients, Bangkok, 1985-2020



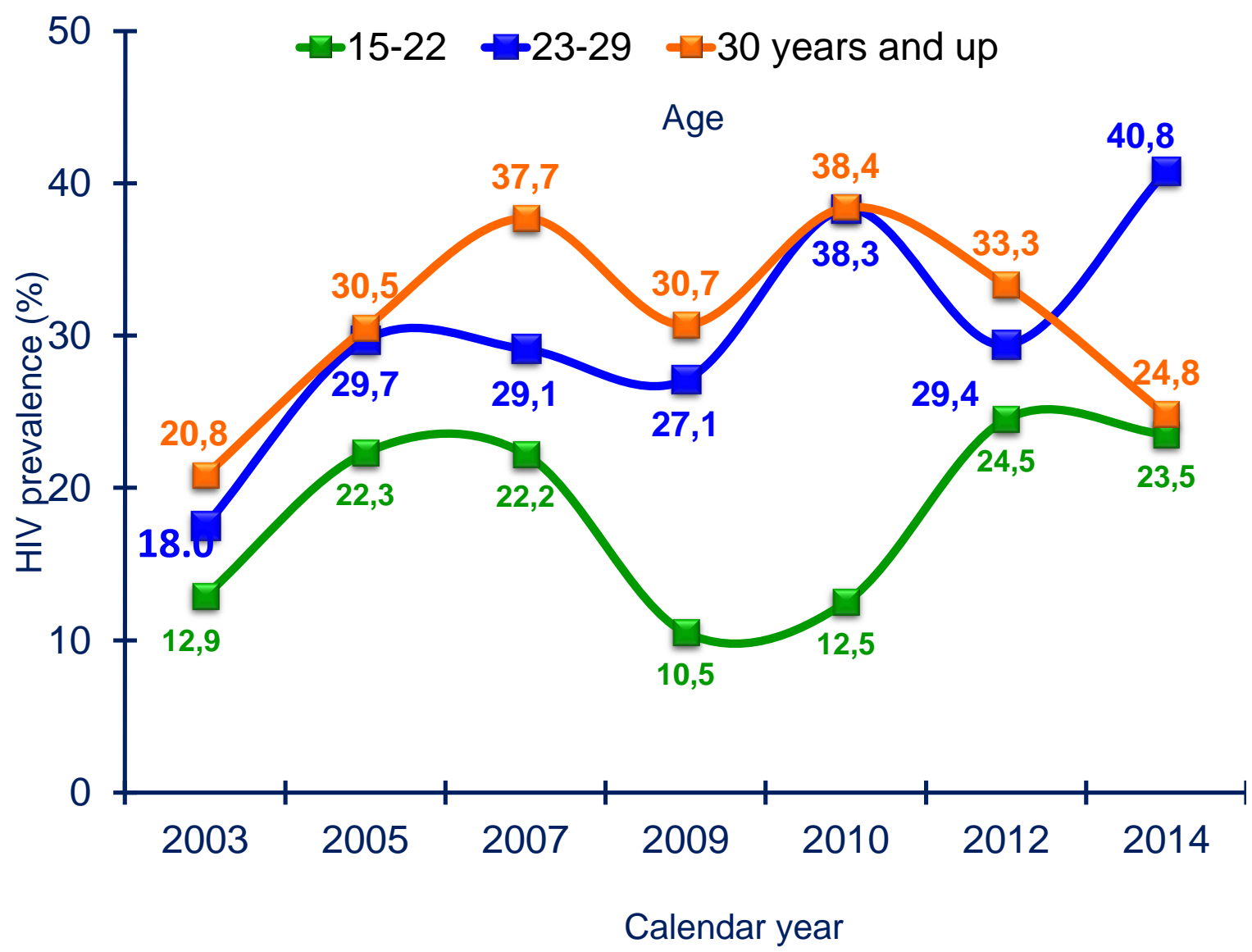
Source: Projections of HIV/AIDS in the Bangkok Metropolitan Administration area , 2014

HIV prevalence in MSM, IBBS, Bangkok, 2003-2014

Source: IBBS, Bureau of Epidemiology, MOPH and AIDS Control Division, BMA, 2015



HIV prevalence in MSM, IBBS, Bangkok, 2003-2014 by age group



HIV incidence among MSM in Thailand

- In a recent cohort study conducted in Pattaya, HIV incidence was **8.2 and 4.28 per 100 PY** among MSM and TGW sex workers, respectively.
- An ongoing 'Test and Treat' cohort among MSM and TGW in Bangkok, Ubon Ratchathani, Lampang and Mahasarakham found a preliminary HIV incidence of **6.12-7.05/100 PY** between November 2012 and September 2014 (Nittaya Phanuphak, unpublished data).

Robb M, et al. NEJM 2016; 374:2120-2130.

Thailand Working Group on HIV/AIDS Projection. AIDS Epidemic Model - Projection for HIV/AIDS in Thailand. 2010-2030. Summary Report Bangkok: Ministry of Public Health, 2012.

Conclusions for HIV epidemic in MSM in Thailand

- Ongoing and expanding HIV epidemics in MSM
- HIV incidence highest in youngest MSM
- Aging of the MSM population, with HIV prevalence levels similar to San Francisco situation in the beginning of the 80's
- HIV viral and behavioral dynamics create an epidemic force that cannot be countered
- Treatment as prevention: the jury is still out; if we can't treat them, we may have no other option than to prevent them.

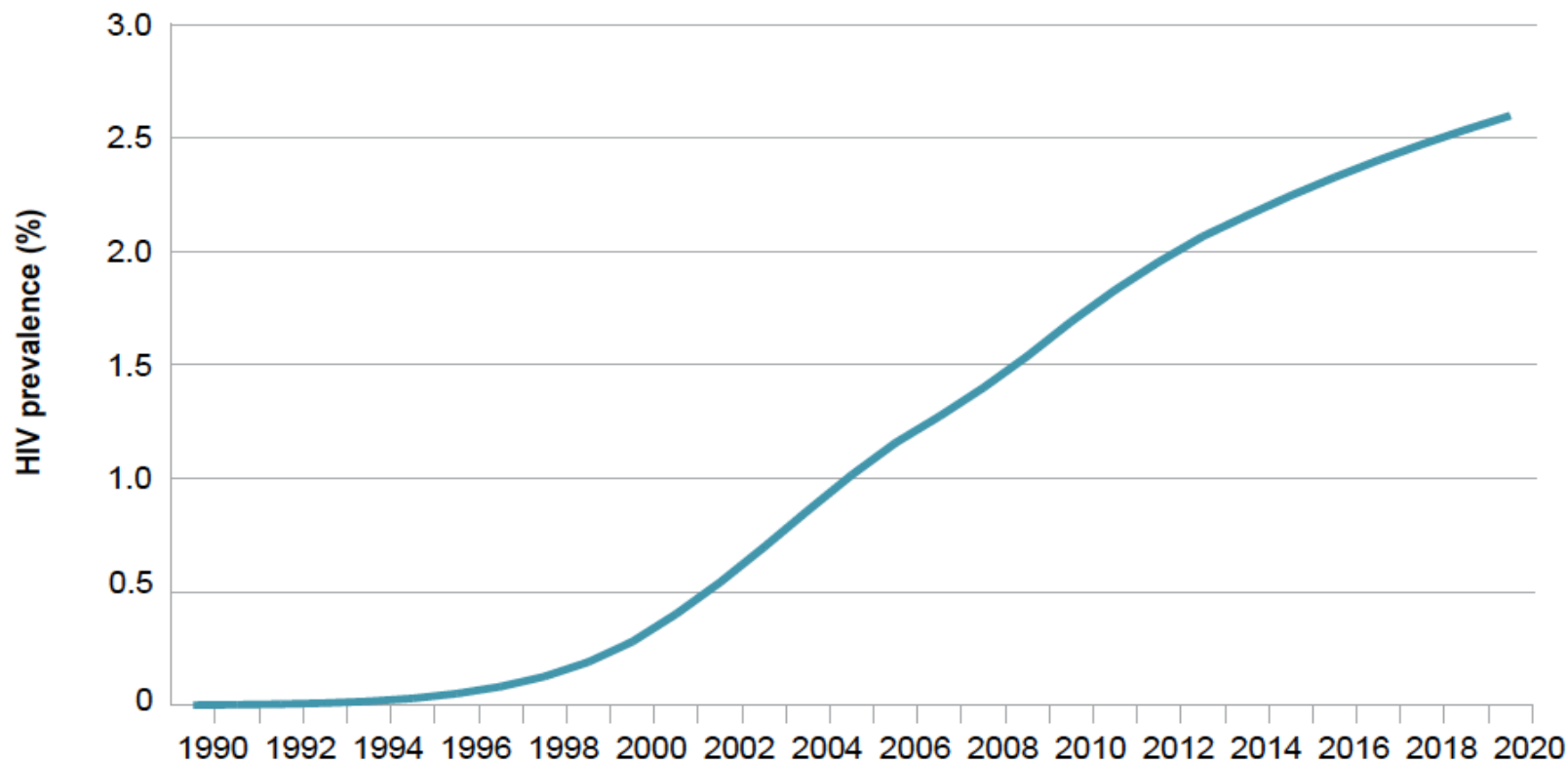
VIETNAM

Key population size estimates, 2013

Population size estimates		
Populations	Estimate	Year of estimate
People who inject drugs	271,506	2013
Female sex workers	71,936	2013
Men who have sex with men	382,506	2013

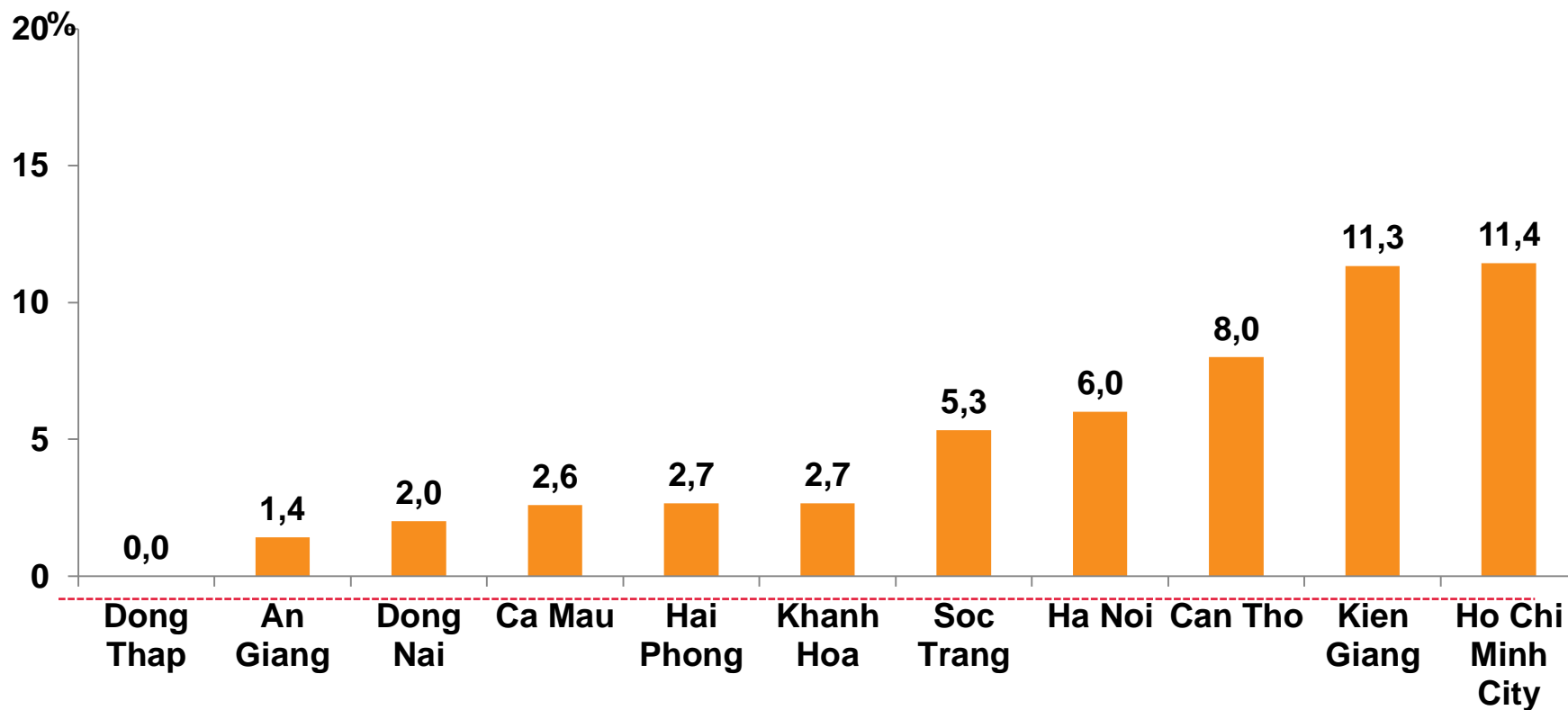
Estimated HIV prevalence in MSM - Vietnam 1990-2020

**Fig. 7: Estimated HIV prevalence among MSM in Viet Nam, 1990–2020:
national prevalence**



Source: Asian Epidemic Model, baseline scenario, VAAC, 2014

HIV prevalence among MSM by city/province, 2015



HIV epidemic in MSM in Vietnam 1

- **Currently estimated overall HIV prevalence 8.2% (2016)**(aidsdatahub.org)
- The national HIV program shifted attention to the risks of acquiring HIV among MSM after results from the IBBS showed a significant rise in HIV prevalence between 2006 and 2009 in **Hanoi and Ho Chi Minh City**, and epidemic modeling estimated a rapid increase in national HIV prevalence among high-risk MSM. MSM were included in sentinel surveillance only in 2011.

HIV epidemic in MSM in Vietnam 2

- The population of MSM in HCMC was estimated to be 37,238, which is 1.35% of the male population.
 - *Safarnejad J Urban Health 2017*
- The overall HIV prevalence trend among MSM in HCMC increased between 2005 and 2013.
- **In 2013, 12% of MSM in HCMC were infected with HIV, and estimated to 14.2% in 2014.**
 - *Joint Review of the Health Sector Response to HIV in Viet Nam 2014, WHO WPRO*
- Overall MSM population not clearly known in Hanoi (likely in the range of 10,000).
- **HIV prevalence in Hanoi was 6.4% (late 2014).**
 - *Vu Front. Public Health 2016*
 - *Nguyen AIDS Behav 2016*
- **No HIV incidence data available in MSM in Vietnam**

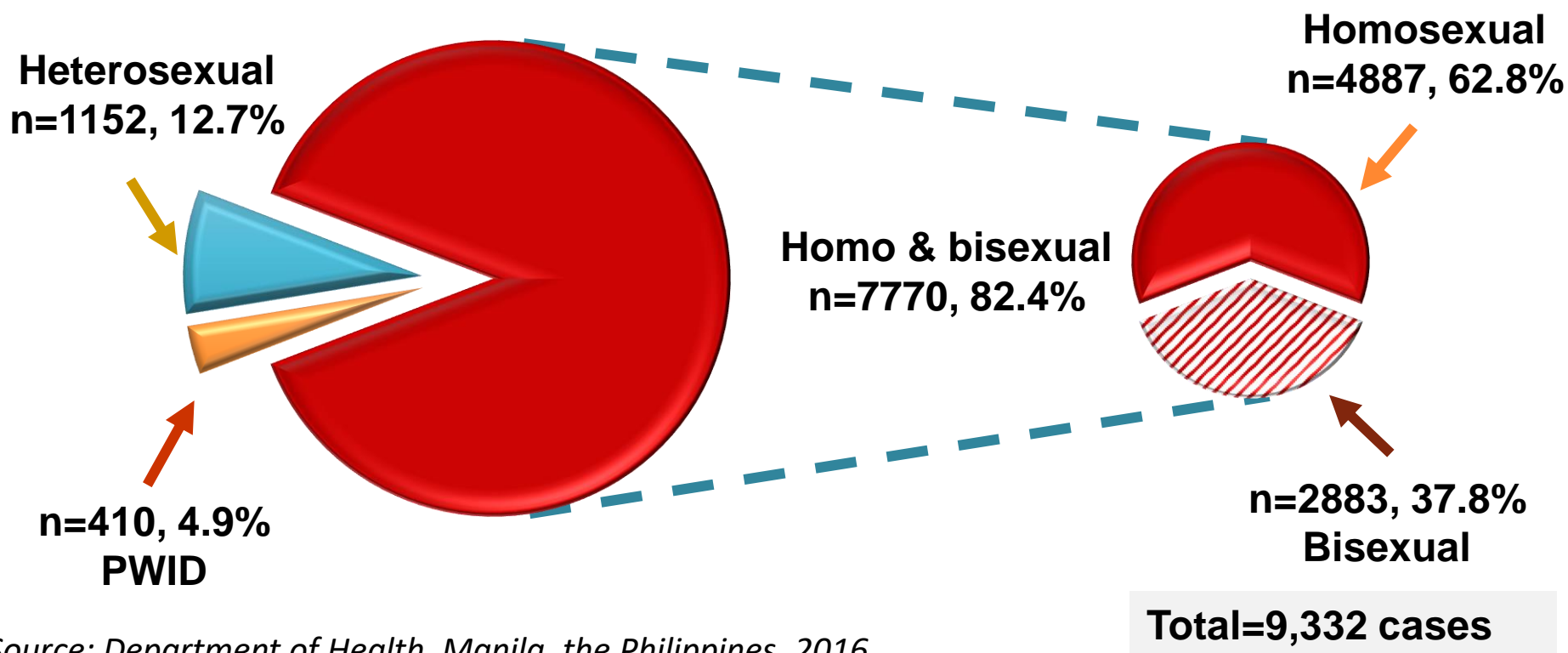
PHILIPPINES



Majority of new HIV infections are among MSM 2015, Philippines

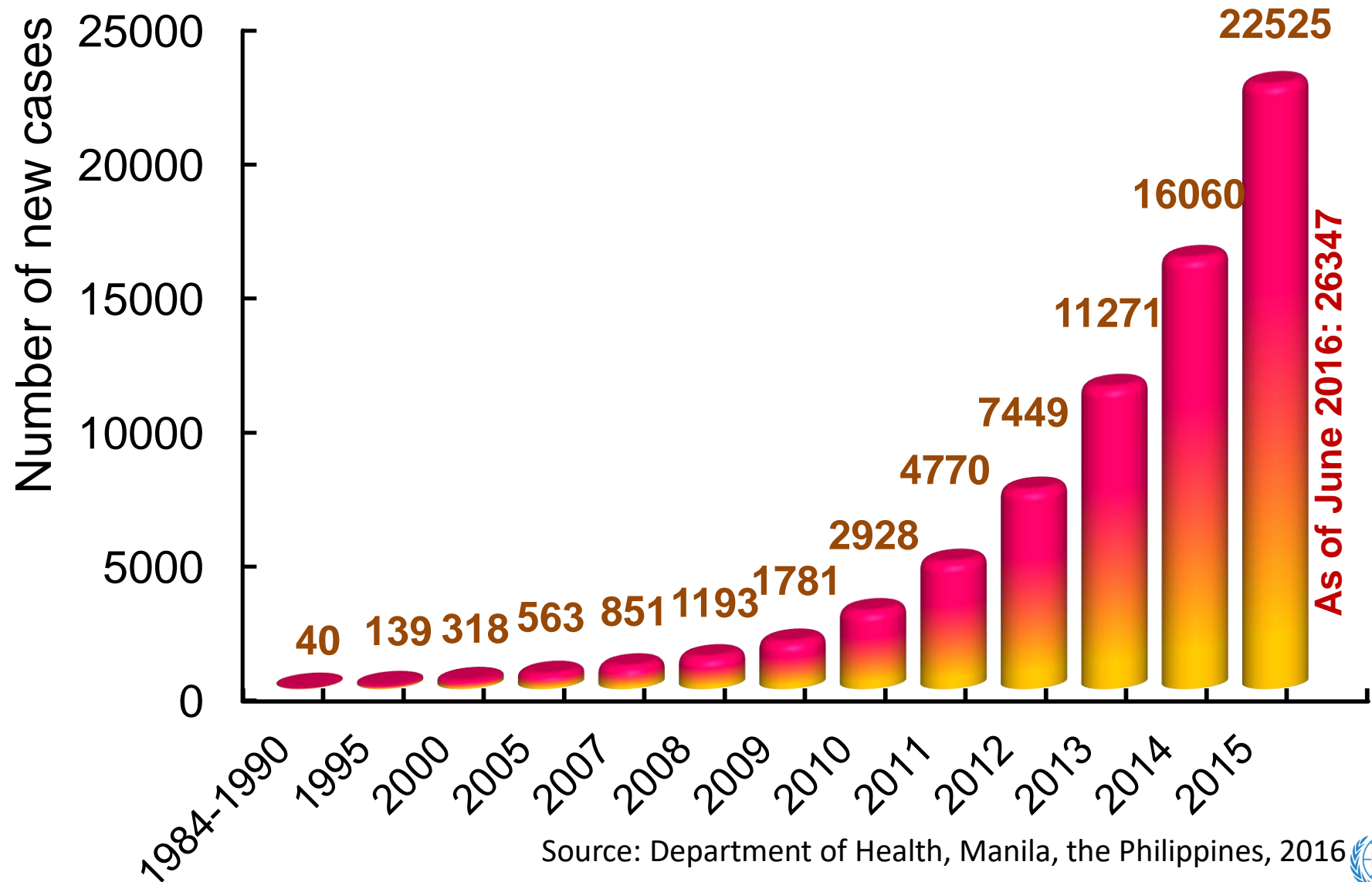
Cumulative reported number of newly diagnosed HIV infections in youth (15 - 24 years), 1984-2016¹, the Philippines, by transmission category

¹up to and including June 2016

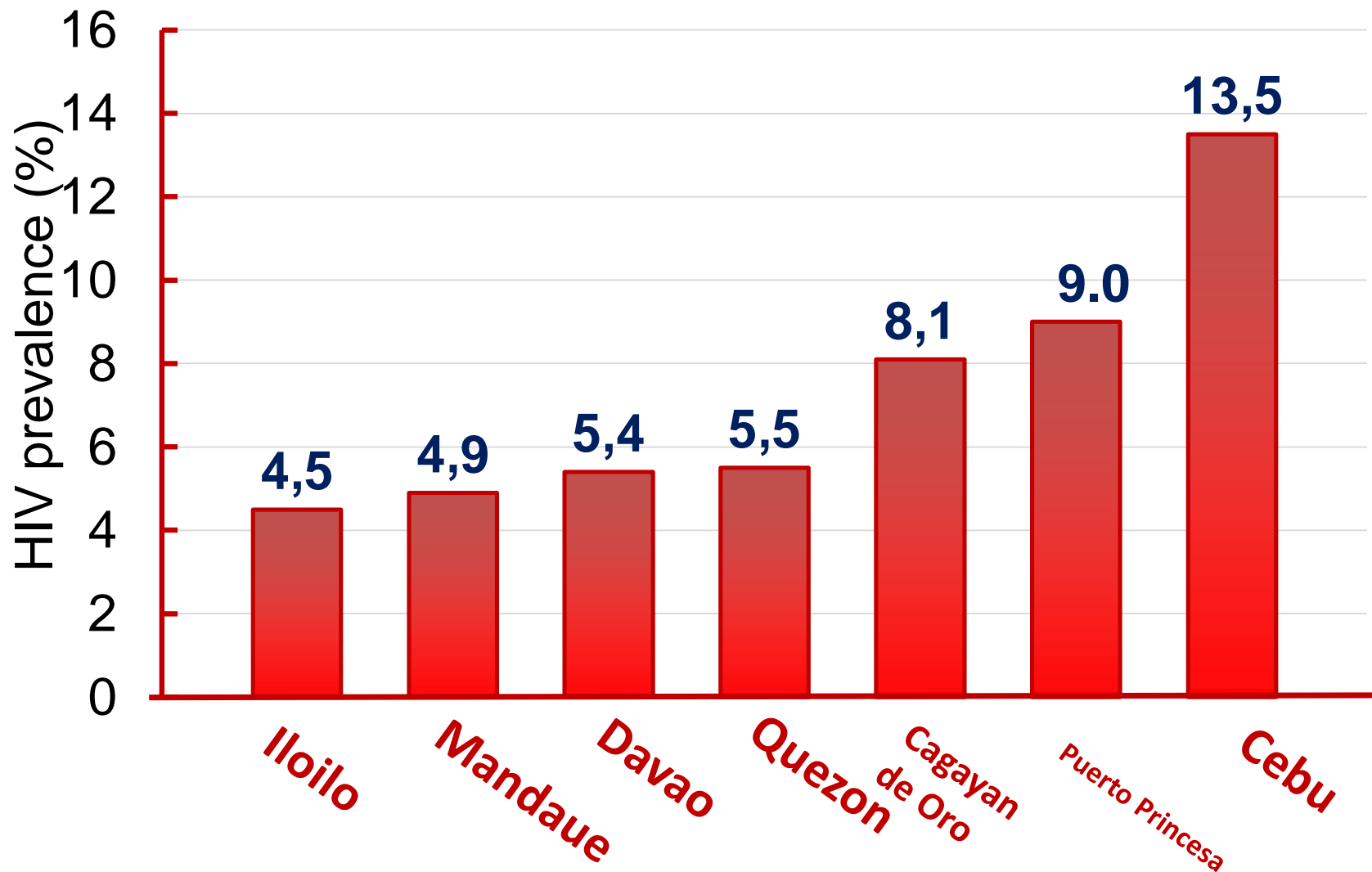


Source: Department of Health, Manila, the Philippines, 2016

Cumulative number of reported newly diagnosed HIV infections in men who have sex with men, the Philippines, 1985-2015



HIV prevalence among MSM in selected surveillance sites, the Philippines, 2015 (7 highest out of 35 sites)



Source: Department of Health, Manila, the Philippines, 2016



LoveYourself (LYS) Foundation, Metro Manila

HIV incidence among MSM and transgender re-testers at Clinic in Manila (2012-2015)

6 per 100 person years

9 per 100 person years among ≤ 21 year old

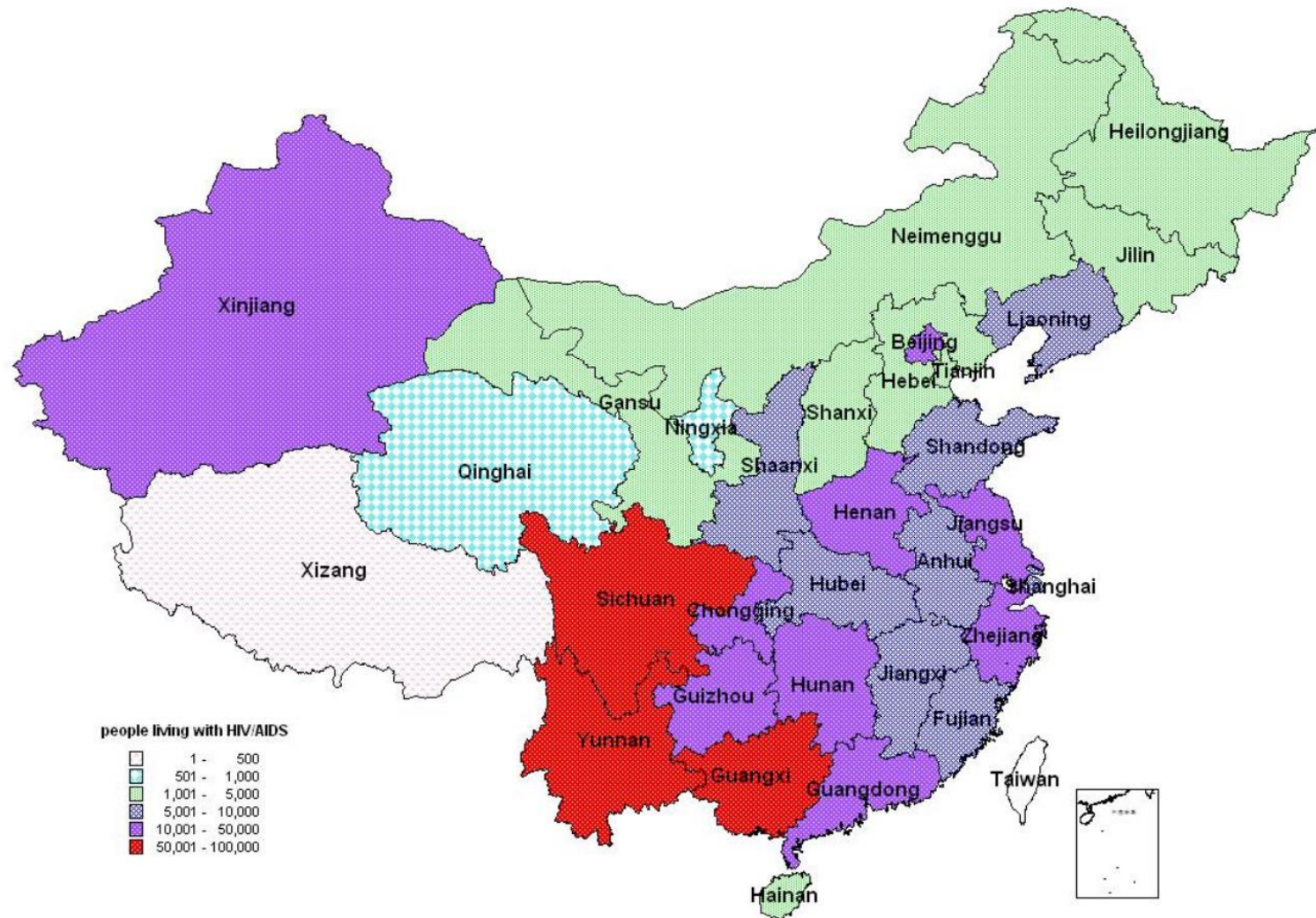
3 per 100 person years among > 21 year old

Source: Clinic Anglo

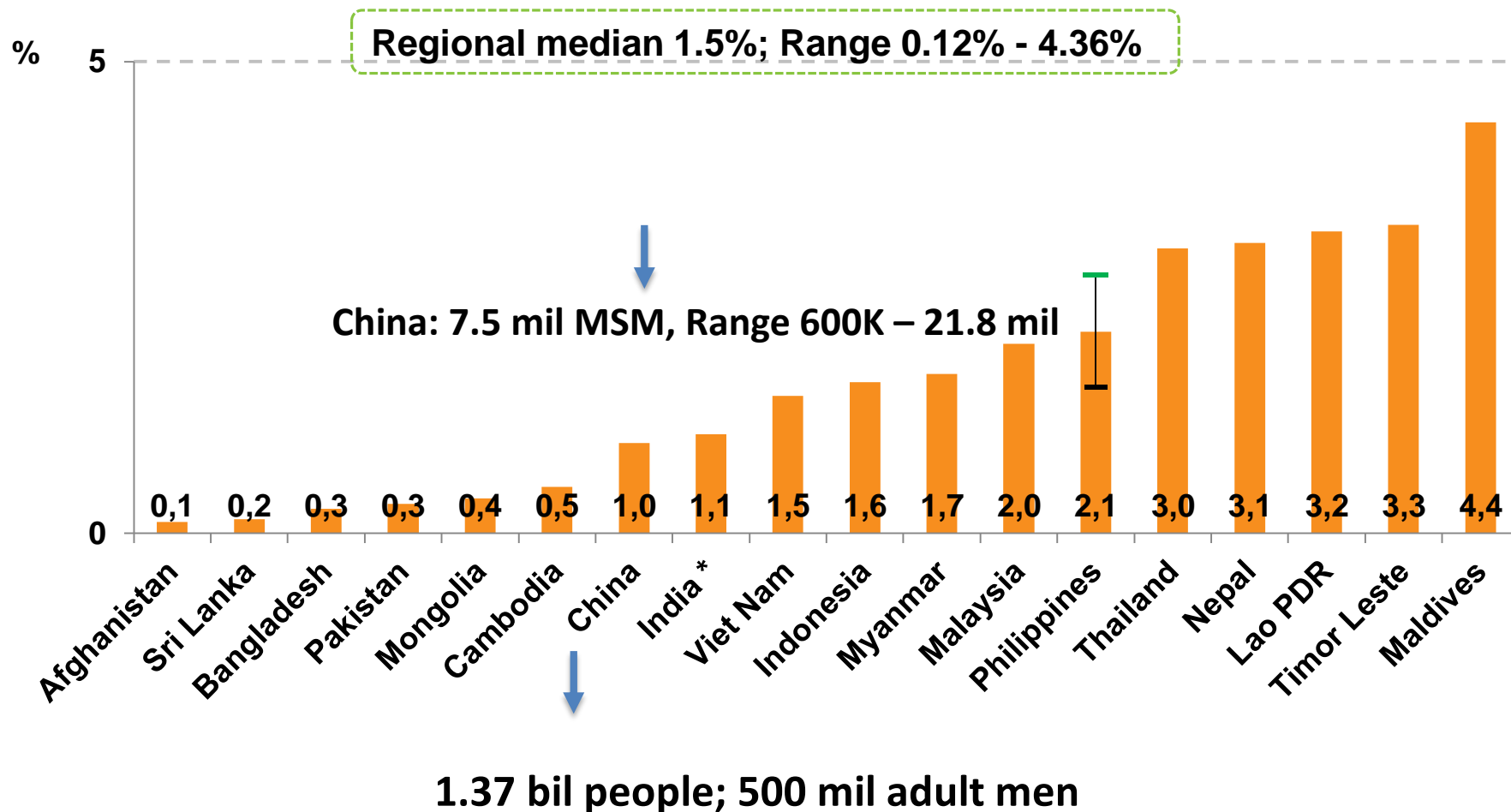


PEOPLE'S REPUBLIC OF CHINA

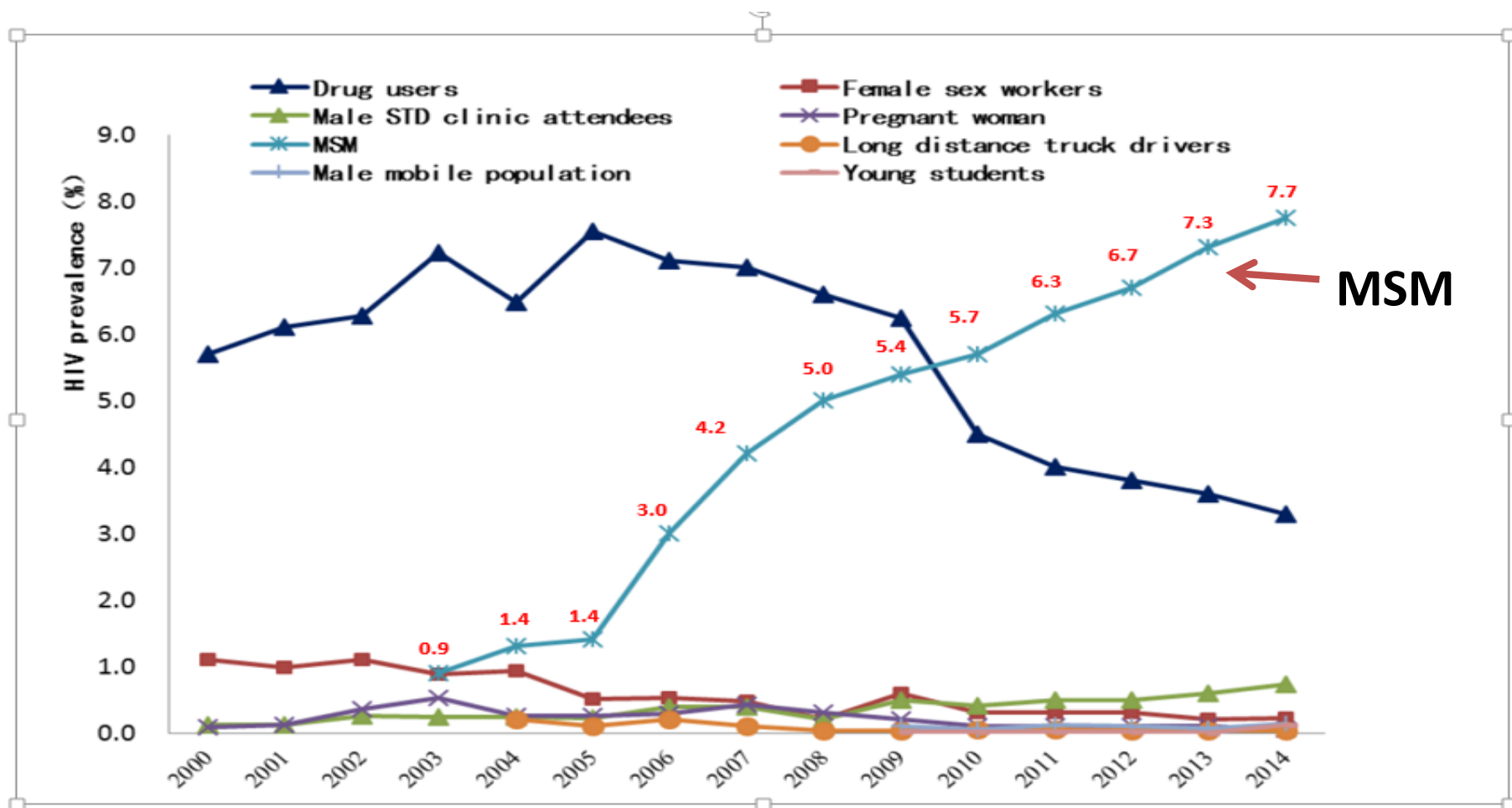
Total number of reported persons living with HIV by province, China, 2014



Size estimates of MSM as proportion of adult male population (15-49) years



HIV prevalence among 8 populations in China's HIV Sentinel Surveillance Surveys (2000-2014)



Estimating HIV incidence in China

- MSM population had the highest incidence estimates at 0.74% in 2011, 0.59% in 2012, 0.57% in 2013 and 0.53% in 2014.

Cui Y et al. JIAS 2016, 19:20609

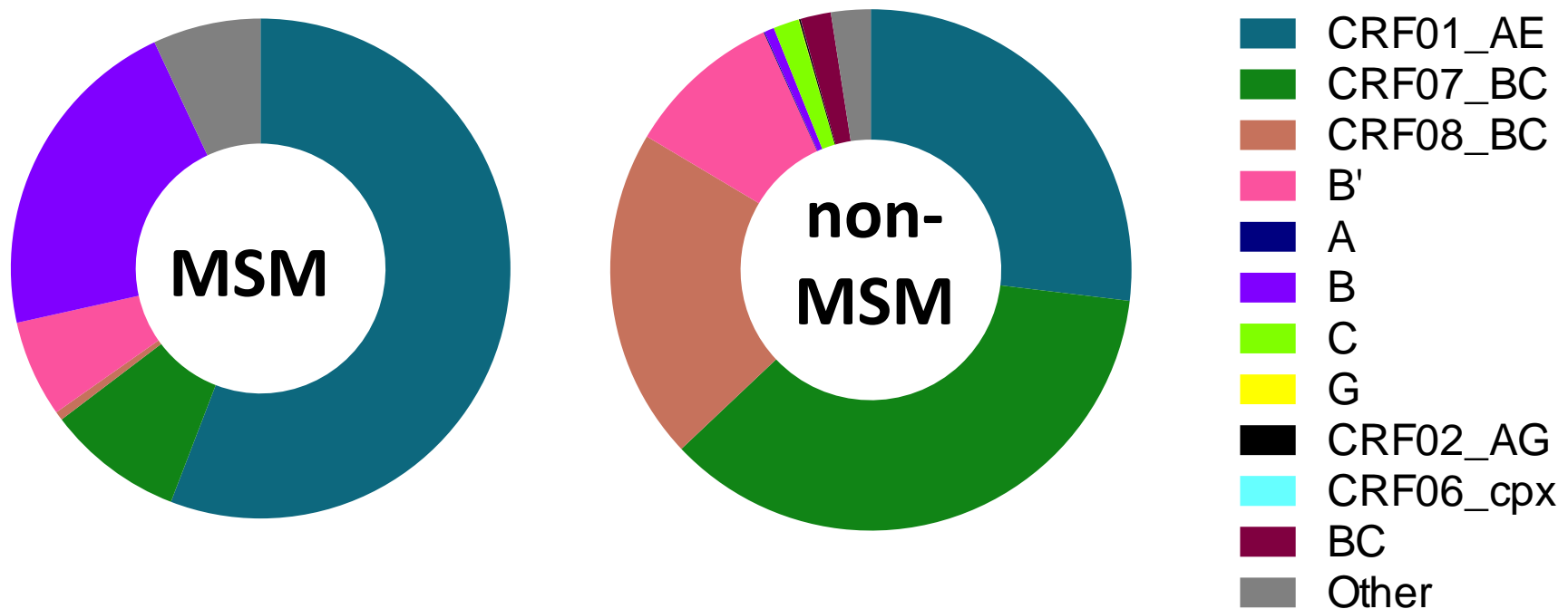
Beijing cohort study 2009-2010 HIV incidence (n=962): 3.90 100 PY (95%CI = 2.37, 5.43).

- *Li D, et al. PLoS ONE 2016; 11(1): e0147422*

Among 4496 eligible MSM recruited in **2012-2013**. The majority was aged ≤ 35 years (77.5 %), migrants (60.3 %), never married (69.8 %), and played receptive role in anal sex (70.5 %).

- The HIV prevalence was 9.9 %, and 41.9 % were recently infected.
- Sensitivity/specificity adjusted **HIV incidence of 8.9/100 PY**.
- Recent HIV infection was associated with having multiple male, recreational drug use, anal bleeding, syphilis and history HSV-2 infection.
 - *Xu et al. Infectious Diseases of Poverty (2016) 5:82*

Estimated HIV subtype distribution MSM vs non-MSM in China



Adapted by David Chang, Sodsai Tovanabutra, Gustavi Kijak, Jean-Louis Excler, Jerome Kim, MHRP
2015 from: He, et al. *A Comprehensive Mapping of HIV-1 Genotypes in Various Risk Groups and Regions across China Based on Nationwide Molecular Epidemiologic Survey*. Plos One. 2012.

CONCLUSIONS 1

- Considerable progress has been achieved in reducing the HIV/AIDS epidemic in Asia over the past decade
- More remains to be done in particular in key populations such as MSM and TGW where the highest prevalence and incidence are found
- Combination of behavioral and biomedical prevention modalities is the only way to go.

CONCLUSIONS 2

- RV144 pave the way to new efficacy trials in both Africa and Asia
- Improvements of the RV144 regimen are on going in Thailand
- Unique opportunity to test a vaccine among mostly CRF01_AE infected MSM and TGW populations

CONCLUSIONS 1

- **Continue focusing efforts in Thailand:**

- ✓ Possible challenges:

- Aging MSM population
- WHO consolidated guidelines on HIV testing, treatment and prevention call for an expanded access to PrEP worldwide and have provided guidance on PrEP implementation in the region
- Several PrEP studies on going (*PrEP-30 Project (Thai Red Cross AIDS Research Centre) and Princess Soamsawali PrEP Project*) and scaled up intervention planned
- PrEP will likely needed to be implemented in the context of HIV vaccine efficacy trials
- HIV incidence may decline as a consequence and compromise the feasibility of an efficacy trial (insufficient endpoints)

Invest efforts and funds in other Asian countries

- ✓ Focusing on Thailand only may be risky and compromise the feasibility of an HIV vaccine efficacy trial (insufficient endpoints)
- ✓ May allow to conduct multi-country and multi-site efficacy trials
- ✓ More funds and manpower will be needed to implement this strategy

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