

A MONITORING AND EVALUATION FRAMEWORK FOR CONCENTRATED EPIDEMICS AND VULNERABLE POPULATIONS

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INTRODUCTION (1)

- ❑ **M&E frameworks historically reflect the logic of generalized epidemics**
- ❑ **They encompass these steps:**
 - ❑ **Assess HIV prevalence in the general population, including age and geographic sub-strata**
 - ❑ **Assess behavioral factors contributing to overall HIV prevalence and sub-strata variations**
 - ❑ **Assess overall scope and coverage of program services, with reference to overall population and sub-strata**
 - ❑ **Triangulate HIV, behavioral and program data, to assess trends**
 - ❑ **In short, they examine the general population, albeit including sub-strata. Analysis of vulnerable groups is usually limited to HIV prevalence and relevant behaviors. The potential size of an epidemic is a function of overall risk behavior**

INTRODUCTION (2)

- Concentrated epidemics require a framework that seeks to better understand vulnerable groups**
- These include what may be termed universal vulnerable groups, specifically injecting drug users (IDU), sex workers (SW) and men having sex with men (MSM). They are universally vulnerable because of behavioral and biological factors**
- In addition, their immediate sexual partners have elevated vulnerability, including clients of SW**
- They also include what may be termed situation-specific vulnerable groups, who may include prisoners and migrants to or from highly affected countries**

INTRODUCTION (3)

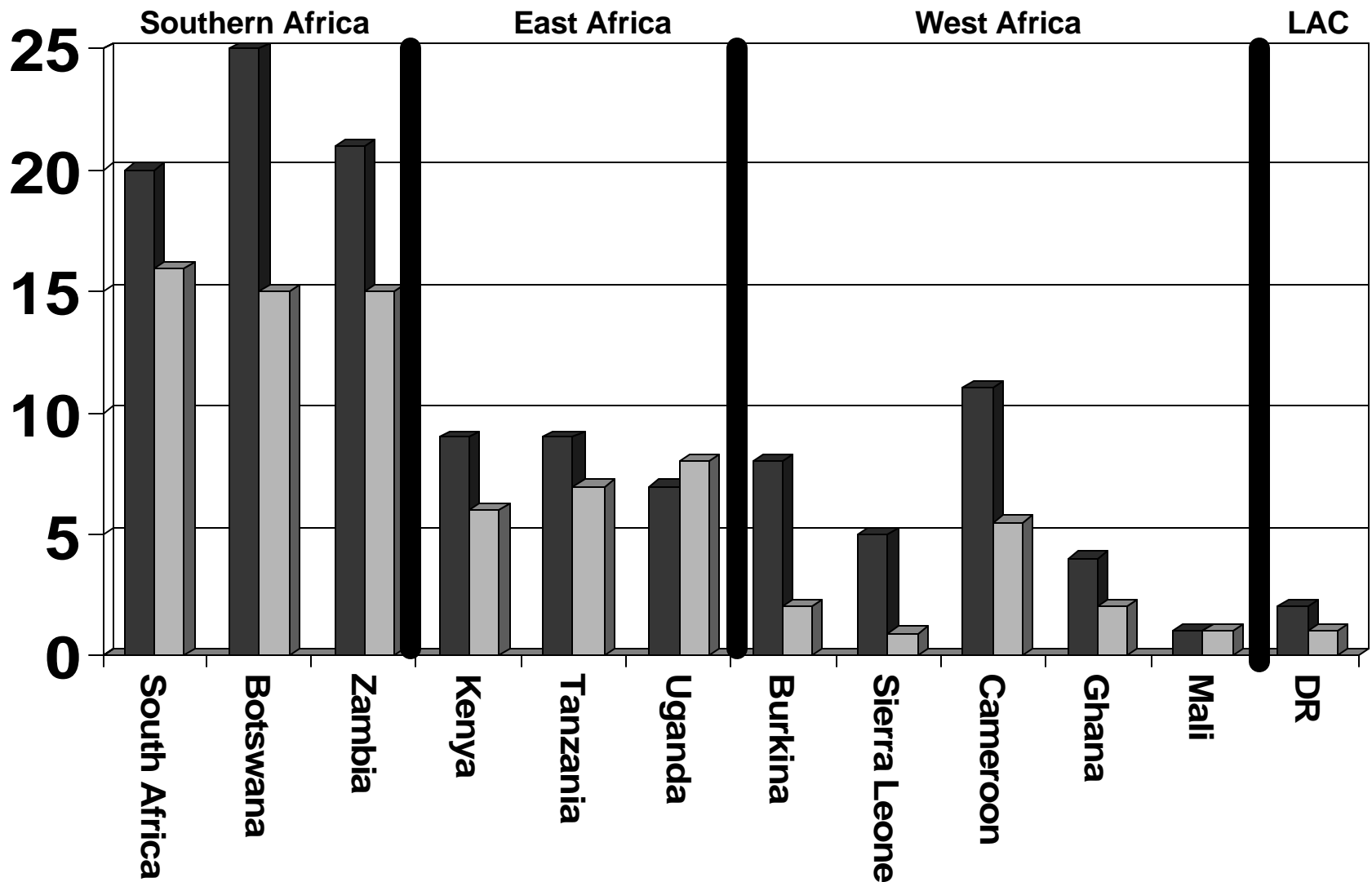
- Historically, epidemics generalized if they exceeded arbitrary threshold, such as 1% or 5% of general population**
- However, formulaic definitions inhibit understanding – need alternative definition**
- Epidemics concentrated if transmission mostly among vulnerable groups and if protecting vulnerable groups would protect wider society**
- Conversely, epidemics generalized if transmission mainly outside vulnerable groups and would continue despite effective vulnerable group interventions**

INTRODUCTION (4)

- Improved population surveillance shows more concentrated epidemics than realized**

ANTENATAL AND POPULATION HIV ESTIMATES

■ ANC ■ POP



Sources: NAC/NAP, 2001-2003, ORC/MACRO

INTRODUCTION (5)

- Major reason – male circumcision**
- Generalized heterosexual transmission rare in highly circumcised populations**
- Other lethal ingredient – concurrent sexual partnerships**
- Male circumcision and concurrent partnerships - the lethal cocktail that creates Southern Africa's explosive epidemics**

INTRODUCTION (6)

- Concentrated epidemics ARE important**
- Consider these official estimates of the size of IDU and SW communities**
- Even if half of these communities and their immediate sexual partners become infected, we'll still have epidemics greater than African countries – because of the size of overall and vulnerable populations, not generalized transmission**

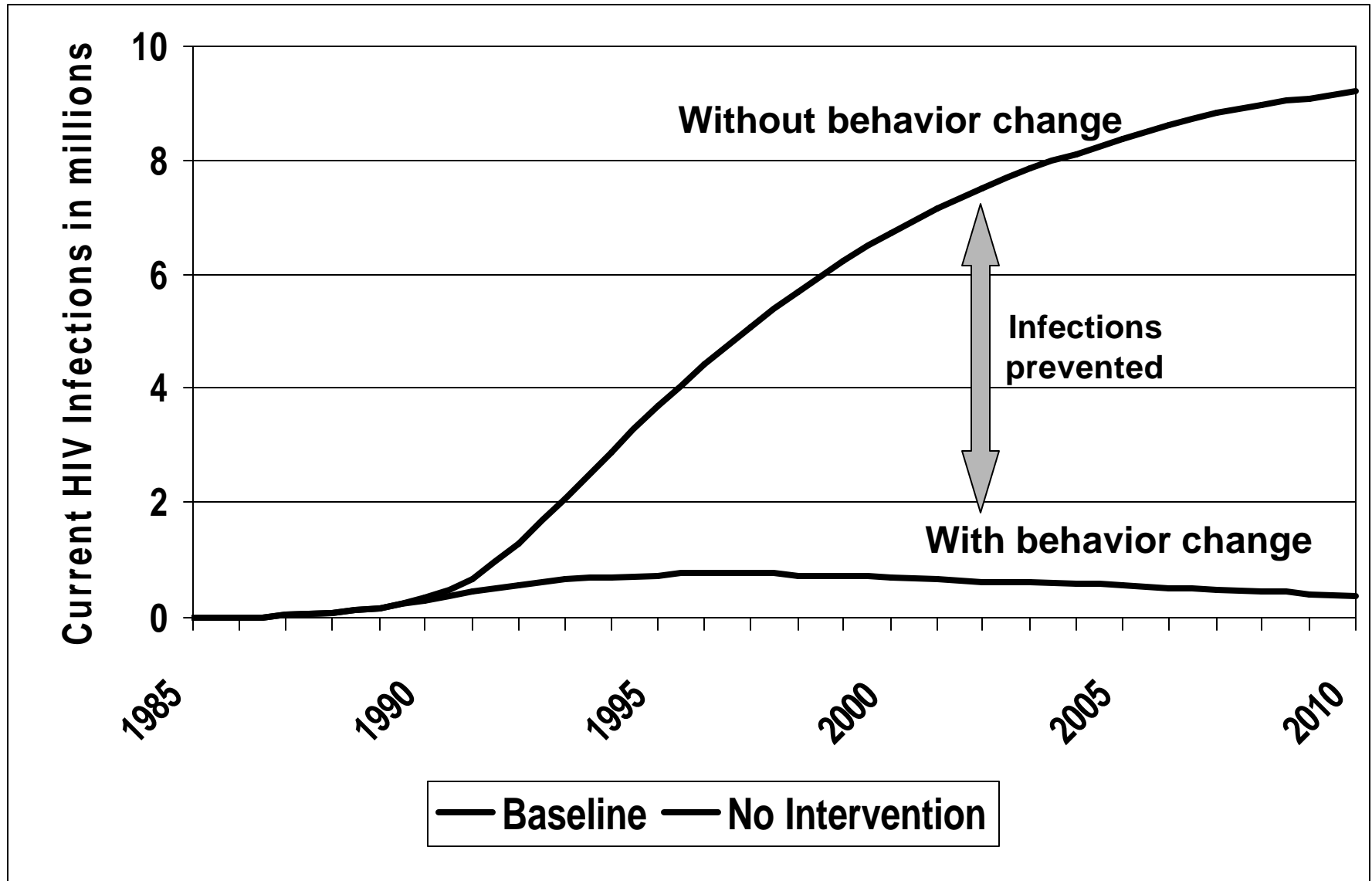
ESTIMATED NUMBERS OF IDU AND SW

Country	IDU	SW
China	1-3 million	3-4 million
Russia	1-3 million	50,000-100,000
India	500,000-1 million	3-4 million
Indonesia	200,000-1 million	190,000-270,000
Ukraine	200,000-500,000	30,000-50,000
Burma	>200,000	>100,000
Indonesia	>200,000	100,000

INTRODUCTION (7)

- Concentrated epidemics are also preventable, with proven, relatively inexpensive prevention responses**
- Effective, early action works – can significantly change contours of epidemic**

EARLY, EFFECTIVE ACTION IN THAILAND



OVERVIEW (1)

The steps in a concentrated epidemic model are to assess:

The problem

Prevalence

Size estimates

Interactions

Estimated proportion of infections

The response

Program services

Coverage

Outcomes

Impacts

HIV PREVALENCE (1)

- HIV prevalence fundamental – the bedrock of surveillance, monitoring and evaluation**
- HIV infection only takes place if there is EXPOSURE - sex or fluid exchange with infected person**
- It doesn't matter how many sexual partners we have or needles we share if we're all uninfected**
- EXPOSURE is everything – which is why HIV prevalence is fundamental**
- Using behavioral without HIV data single greatest cause of bad programming**

HIV PREVALENCE (2)

- HIV prevalence assessed by focused bio-surveys - may include other relevant pathogens - STIs among SW or BBVs among IDU**
- Bio-surveys may be combined with behavioral surveys – second generation surveillance**
- But HIV prevalence paramount – multiple sexual partnerships including sex work may occur without HIV infection – for example, SW in Chile, Netherlands, Slovenia, Sri Lanka, Philippines, Australia, Fiji**
- This doesn't mean we don't have to keep SW, IDU, MSM safe – we must. For behavioral and biological reasons, wherever SW, IDU, MSM exist, some risk exists and we must program to minimize it**
- Nevertheless, HIV prevalence first step in M&E chain for concentrated epidemics – without growing or significant HIV prevalence - other steps less relevant**

HIV PREVALENCE (3)

- ❑ In concentrated epidemics, HIV occurs primarily in hidden populations - IDU, SW and MSM**
- ❑ HIV testing methods now more diverse, rapid, affordable**
- ❑ But hidden populations lack sampling frames and often prefer to remain concealed, because their behaviors are illegal or stigmatized**
- ❑ Meaningful surveillance depends crucially on representative sampling – for example, HIV prevalence among IDU in Russia or SW in China**
- ❑ Sampling greatest impediment to sound surveillance of vulnerable groups**
- ❑ Following analysis based on CDC and FHI efforts to improve sampling**

HIV PREVALENCE (4)

Routine surveillance

- Based on disease care reporting from health and social services, including hospitals, health centres, private doctors and drug treatment facilities**

HIV PREVALENCE (5)

Routine surveillance

Advantages

□ Relatively simple and inexpensive, as it relies on routine, ongoing case reporting

Disadvantages

□ Requires excellent health and social services and functioning reporting

□ Majority of vulnerable groups must be in regular contact with health system – which is rare

HIV PREVALENCE (6)

Facility sampling

- Involves recruiting samples from facilities used by members, including STI clinics, SW clinics, needle exchange programs, treatment centres and correctional services

HIV PREVALENCE (7)

Facility sampling

Advantages

Takes advantage of existing facilities and services

Disadvantages

Few facilities for many vulnerable groups, especially in developing countries

Those using services often atypical - unrepresentative

HIV PREVALENCE (8)

Chain referral or snowball sampling

- Involves identifying initial numbers of vulnerable groups as seed participants, who help to identify and recruit other participants, who in turn identify and recruit others, until sample size reached or sample is saturated**

HIV PREVALENCE (9)

Chain referral or snowball sampling

Advantages

- Historically effective way of reaching hidden communities
- Still useful in situation assessment and problem definition

Disadvantages

- Initial seeds hardly ever randomly chosen – thus non-random convenience sampling method
- Heavily influenced by initial seeds
- Favors cooperative rather than randomly chosen participants

HIV PREVALENCE (10)

Targeted sampling

- ❑ Uses initial ethnographic analysis to identify discrete sub-groups and networks of vulnerable groups
- ❑ The different sub-groups are then treated as separate strata and quota samples chosen within each stratum

HIV PREVALENCE (11)

Target sampling

Advantages

If ethnographic sample is thorough, produces more representative sample and reduces bias

Disadvantages

Initial ethnographic assessment lengthy and costly

Remains non-probability, convenience sample

HIV PREVALENCE (12)

Time-location sampling

- Based on tendency of some vulnerable group members to gather at certain locations – for example, IDU in shooting galleries or dealing areas, SW in brothels, massage parlors, red light districts, certain streets, MSM in gay bars or cruising areas
- Different sites are enumerated in ethnographic and mapping studies
- List of sites then used as sampling frame from which to select probability sample of sites
- Interviews then done at randomly chosen 3 hour interval on randomly chosen day of week

HIV PREVALENCE (13)

Target sampling

Advantages

Because inclusion probabilities may be calculated, this approximates a probability sampling method

Disadvantages

Unless high proportion of members visit selected sites and unless high proportion of all such sites are identified during enumeration, significant bias exists

As gathering places change over time, enumeration must be repeated before each survey round

Members who do not visit enumerated sites are major source of bias

Many people at recruitment sites may be reluctant to participate in surveys – for example, IDU buying drugs, sex workers at street corners, MSM at beats

HIV PREVALENCE (14)

Respondent driven sampling (RDS)

- Magnani et al note that RDS resembles snowball sampling in that it begins with chain referral sampling
- However, recruitment is done in a way that allows for calculation of selection probabilities, thus qualifying it as a probability method
- In RDS, seeds are recruited as temporary recruiters. They each receive a limited number of coupons (usually 3-4) with unique serial numbers to enroll peers

HIV PREVALENCE (15)

Respondent driven sampling (RDS)

- If the recruited peer is eligible, the recruiter receives modest compensation
- Each referred participant, and their referred participants, continue to receive coupons and compensation, until the sample reaches saturation
- RDS thus uses a dual recruitment system of peer influence and financial incentives, which may broaden participation
- Because participants must present themselves to enroll, recruitment is wholly voluntary and anonymous

HIV PREVALENCE (16)

Respondent driven sampling (RDS)

- ❑ In RDS, coupons limit the number of participants each seed can recruit, dampening recruitment bias and encouraging diverse recruitment chains, which reach into more concealed populations**
- ❑ Relationship between recruiter and recruits is documented, so recruitment biases can be assessed and adjusted for during analysis**
- ❑ Information of network size is collected to permit weighted analysis through post-stratification**
- ❑ In RDS, sampling frames are constructed during sampling processes, obviating the need for extensive preparatory ethnography and mapping**
- ❑ RDS samples proceed through successive cycles until the sample reaches equilibrium, usually within six waves**

HIV PREVALENCE (17)

Respondent driven sampling (RDS)

□ Four prerequisites are:

□ Recruitment chains are documented, usually through coupons

□ Recruitment rationed to 3-4 coupons per seed

□ Personal network information collected

□ Recruiters and participants must know each other

HIV PREVALENCE (18)

- RDS new but recent studies support its use:**
- Increased estimated size of IDU population in Connecticut 10-fold**
- Increased estimated size of MSM population in three US cities by 50%**
- Revealed hidden overlap between IDU and SW networks in Vietnam**

HIV PREVALENCE (19)

Respondent driven sampling

Advantages

- Qualifies as probability method
- Dampens recruitment bias from long chains
- Use of multiple diverse chains enables sample to reach more deeply into hidden populations
- Reducing masking bias by self-referral and anonymity
- Increases participation, by offering dual incentives, including financial incentives
- Has demonstrated ability to reach larger samples of hidden populations

Disadvantages

- Limited documentation and professional experience with RDS in developing countries

SIZE ESTIMATION (1)

- Prevalence only meaningful when supported by size estimation**
- For example, HIV prevalence among IDU in the Pacific Island of *Imagineri* (population 300,000) is 50%. The public health implications are vital if there are 10,000 IDU, but less critical if there are 10 IDU**
- Prevalence and size estimation are inseparable in sound analysis**

SIZE ESTIMATION (2)

- How do we estimate the size of vulnerable populations – usually hidden populations?
- Pisani and others describe several methods, including:
 - Delphi
 - Census
 - Enumeration
 - Population survey
 - Multiplier methods
 - Capture-recapture
 - RDS

SIZE ESTIMATION (3)

Delphi

- We ask experts to estimate – IDU in San Francisco
- Basically how first global coverage estimates were done

SIZE ESTIMATION (4)

Delphi

Advantages

- Quick and cheap
- If genuine experts are chosen, can delineate orders of magnitude and provide an informed starting point for programs

Disadvantages

- Not an empirical method, mainly used as a starting point until there are data

SIZE ESTIMATION (5)

Census

- Census methods basically try to count every member of a population
- Example – 6,500 sex workers counted one Saturday night in all city bars

SIZE ESTIMATION (6)

Census

Advantages

Simple and cheap

Disadvantages

Must be done very quickly, to avoid double counts

Unsuitable to concealed populations

SIZE ESTIMATION (7)

Enumeration

- Enumeration methods start with a sampling frame, choose a sample of units, count all people in those units, then multiply by the sampling frame
- Example – From 90 known gay bars, health workers visit 30 and count 100 patrons. They multiply this number by 3 to obtain an estimate of 300 gay men ($100 \times 3 = 300$)

SIZE ESTIMATION (8)

Enumeration

Advantages

- ❑ Even simpler and cheaper than census methods
- ❑ Mathematically straightforward

Disadvantages

- ❑ Also unsuited to concealed populations
- ❑ Sampling frame not always available

SIZE ESTIMATION (9)

Population surveys

- ❑ Population surveys start with sampling frame, ideally households and administer behavioral questionnaires. The prevalence of risk behaviors - including buying or selling sex, men having sex with men and injecting drugs - is then assessed
- ❑ Example – In household survey, 50% of representative sample of men in city with 1 million adult men report having paid for sex in the last year, which suggests a minimum of 500,000 men are clients of sex workers ($0.5 \times 1,000,000 = 500,000$)

SIZE ESTIMATION (10)

Population surveys

Advantages

Give excellent results for behaviors which are found in general population and are relatively acceptable

Disadvantages

Requires representative sampling frame, not sample selected for probable high risk behavior, such as soldiers or prisoners

Unsuitable for behaviors that are rare at household level, occur largely among hidden populations or socially undesirable, such as injecting drug use

SIZE ESTIMATION (11)

Multiplier methods

- ❑ **Multiplier methods use information from two overlapping sources, such as (i) a service the population uses and (ii) the population at risk. The number using the service is then multiplied by the inverse proportion of those attending the service**
- ❑ **Example – 500 registered sex workers attend a compulsory city STI clinic. A behavioral survey shows that 50% of sex workers reported attending the clinic, suggesting the city may have 1,000 sex workers ($500 / 0.5 = 1,000$)**
- ❑ **Example – Behavioral surveys show that 50% of 1 million adult men nationwide visit sex workers on average 10 times a year. Behavioral surveys suggest that sex workers have an average of 50 clients a year, suggesting that the country may have 1,000 sex workers ($[1,000,000 \times 0.5 \times 0.10] / 50 = 1,000$)**

SIZE ESTIMATION (12)

Advantages

- Straightforward

Disadvantages

- Require good service and behavioral data
- Require data from services and populations that correspond with other, in which the population have a chance of being included in the service and population data collection
- Time periods, age ranges and catchment areas must be aligned

SIZE ESTIMATION (13)

Capture-recapture

- ❑ Originated among naturalists, trying to estimate size of fish or elephant populations by tagging, releasing and re-tagging creatures. The number tagged is multiplied by the inverse proportion re-tagged to estimate the total population
- ❑ Example – Survey team visit all known IDU shooting galleries, count 500 IDU, administer a short questionnaire, give them a token denoting date and site and return one week later and interview 400 IDU. They obtain 100 double counts or re-tags. The estimated IDU population is 2,000 ($500 * 400 / 100$)
- ❑ Example – 1,000 IDU are enrolled in an opiate treatment program and 600 IDU are detained by police . 400 IDU appear on both the treatment and police lists. The estimated IDU population is 1,500 ($1,000 * 600 / 400$)

SIZE ESTIMATION (14)

Advantages

- ❑ Useful for estimating size of hidden populations in regular contact with two facilities or services
- ❑ Multiple recaptures greatly improve accuracy

Disadvantages

- ❑ Only highly reliable when (a) samples are uncorrelated (b) each member has an equal probability of capture (c) recaptures are correctly identified and (d) there are closed populations with no major migration in or out between captures. These conditions are rarely met
- ❑ Positively correlated samples underestimate and negatively correlated samples overestimate true size

SIZE ESTIMATION (15)

Respondent Driven Sampling (RDS)

- **RDS, described above, is genuinely independent of the above methods and can significantly improve the accuracy of size estimates**

INTERACTIONS (1)

- HIV prevalence and size estimates for vulnerable populations are important steps to estimate potential HIV prevalence**
- However, we need more – we need to know the interactions among vulnerable groups including IDU, sex workers and MSM and between these groups and the wider community**
- Historically, there has been great debate – are concentrated epidemics, especially IDU epidemics, sequestered (isolated) epidemics or overlapping epidemics?**

INTERACTIONS (2)

Interactions among vulnerable groups

- Do IDU serve as male or female sex workers – perhaps for money for drugs?
- Do male or female sex workers inject drugs – perhaps to dull their consciousness?
- Do sex workers have sexual partners from other vulnerable groups, such as injecting drug users?

INTERACTIONS (3)

Interactions between vulnerable groups and general population

Do male sex workers have boyfriends – with whom they may be less likely to use condoms?

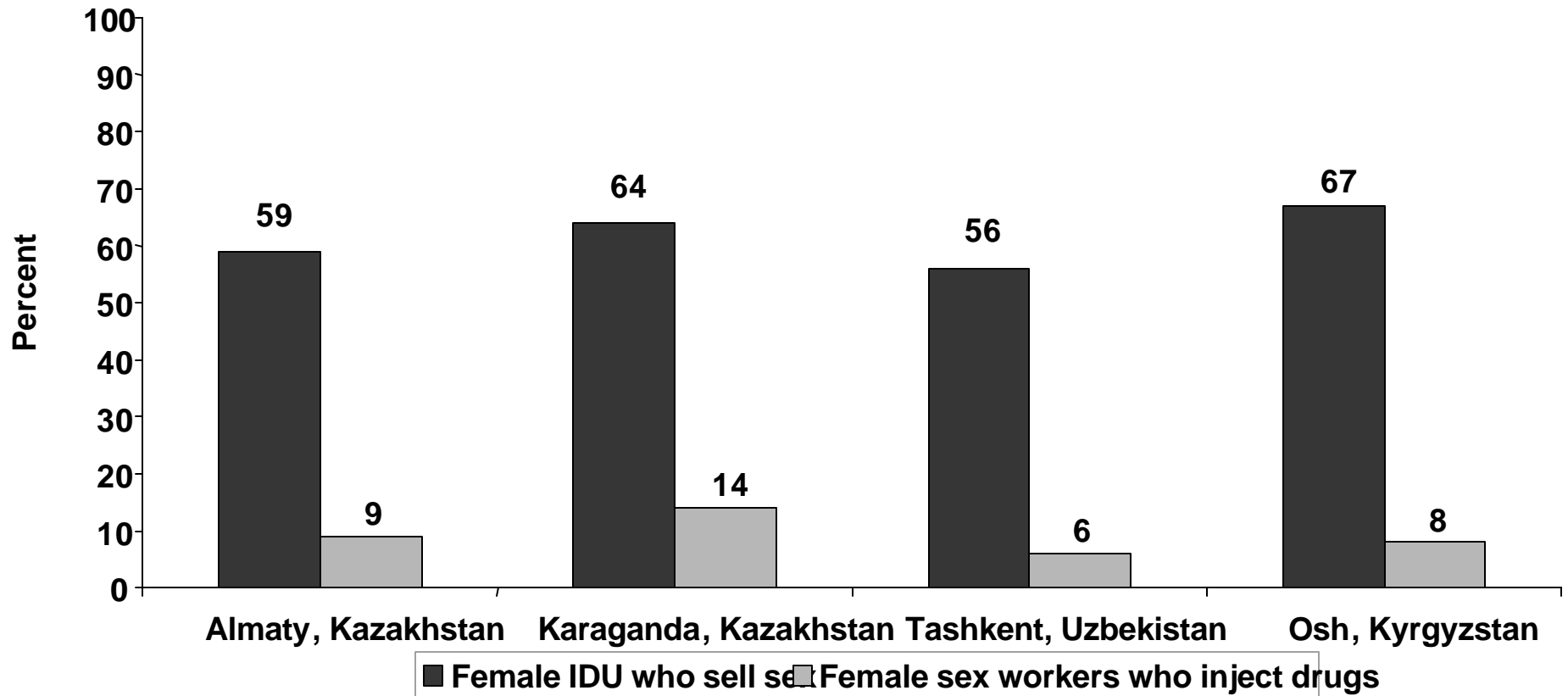
Do male sex workers have girlfriends – with whom they may be less likely to use condoms?

Do female sex workers have boyfriends – with whom they may be less likely to use condoms?

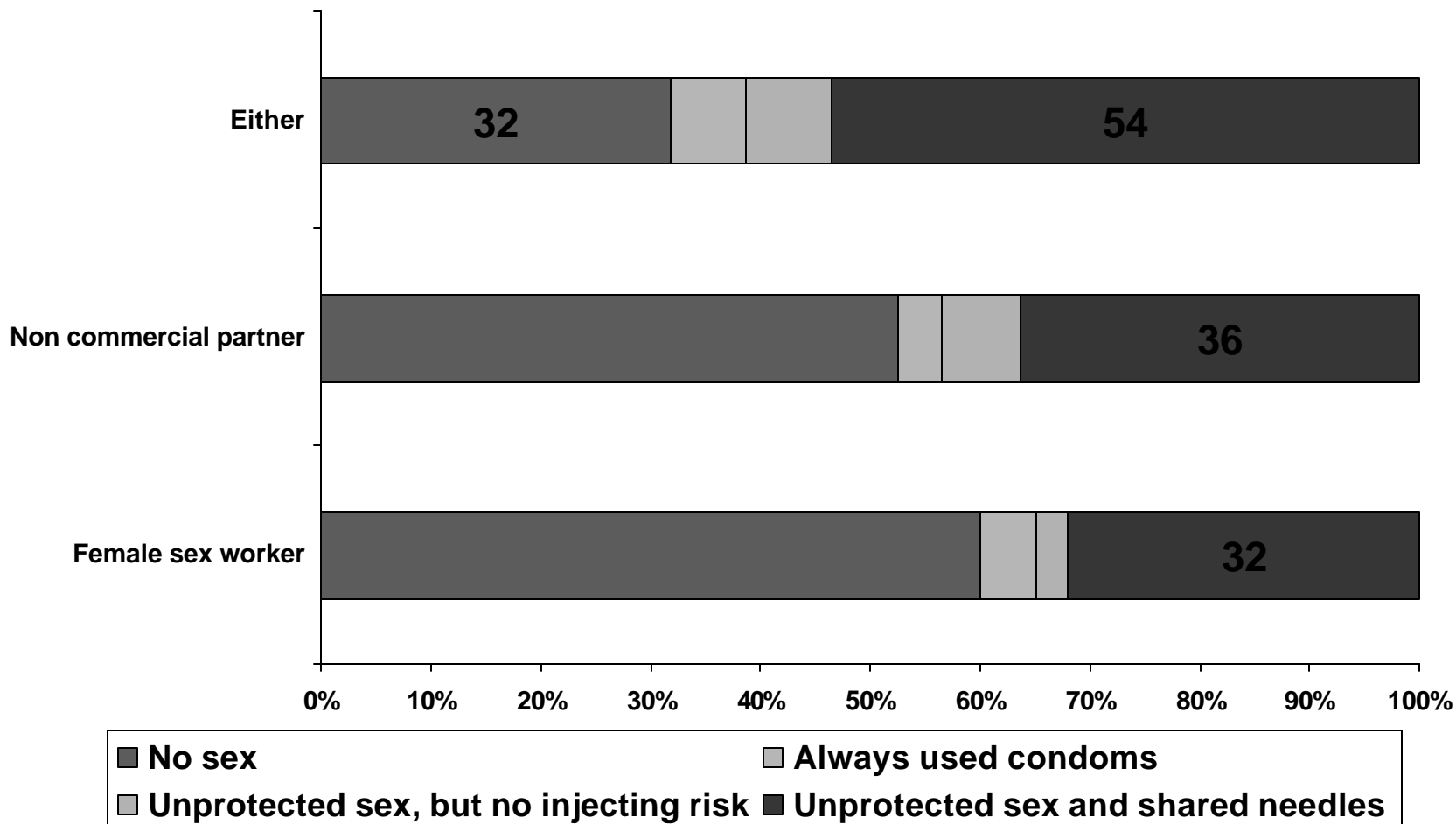
INTERACTIONS (4)

□ While a minority of people in Eastern Europe, Middle East and Asia may be at risk for HIV, those at risk often have multiple risks

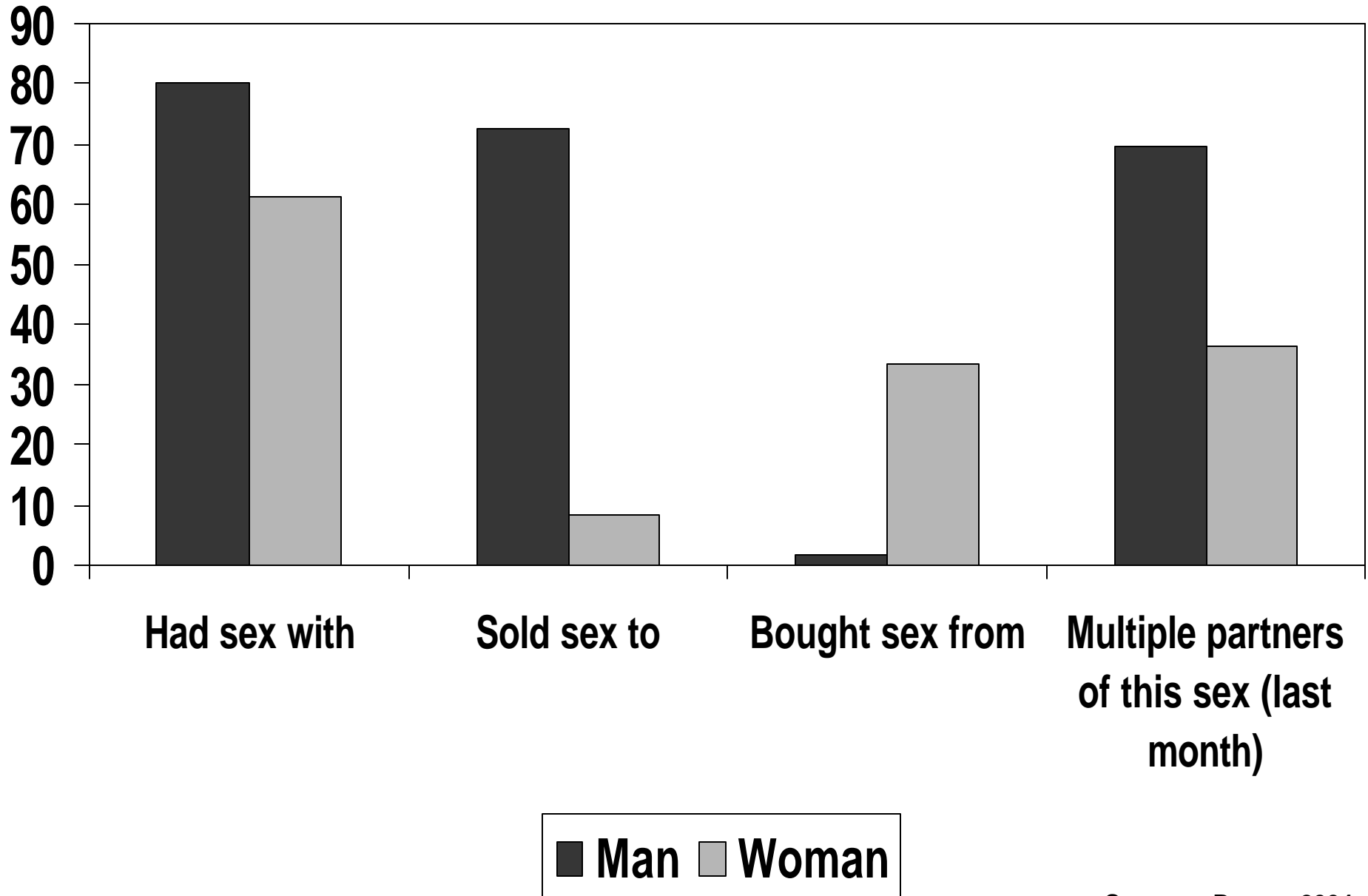
SEX WORKERS WHO INJECT DRUGS IN CENTRAL ASIA



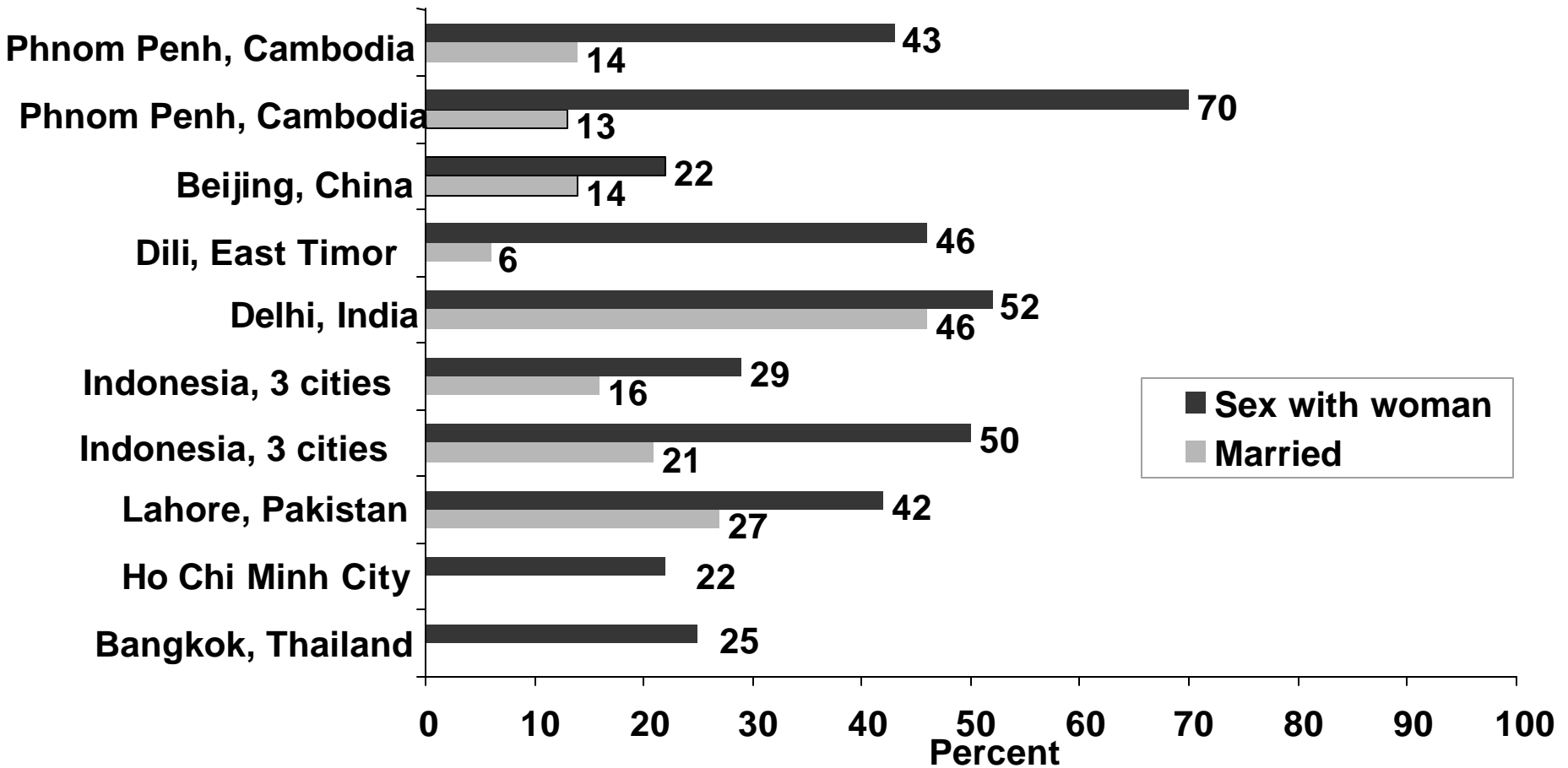
IDU IN INDONESIA WHO SHARE NEEDLES AND HAVE UNPROTECTED SEX



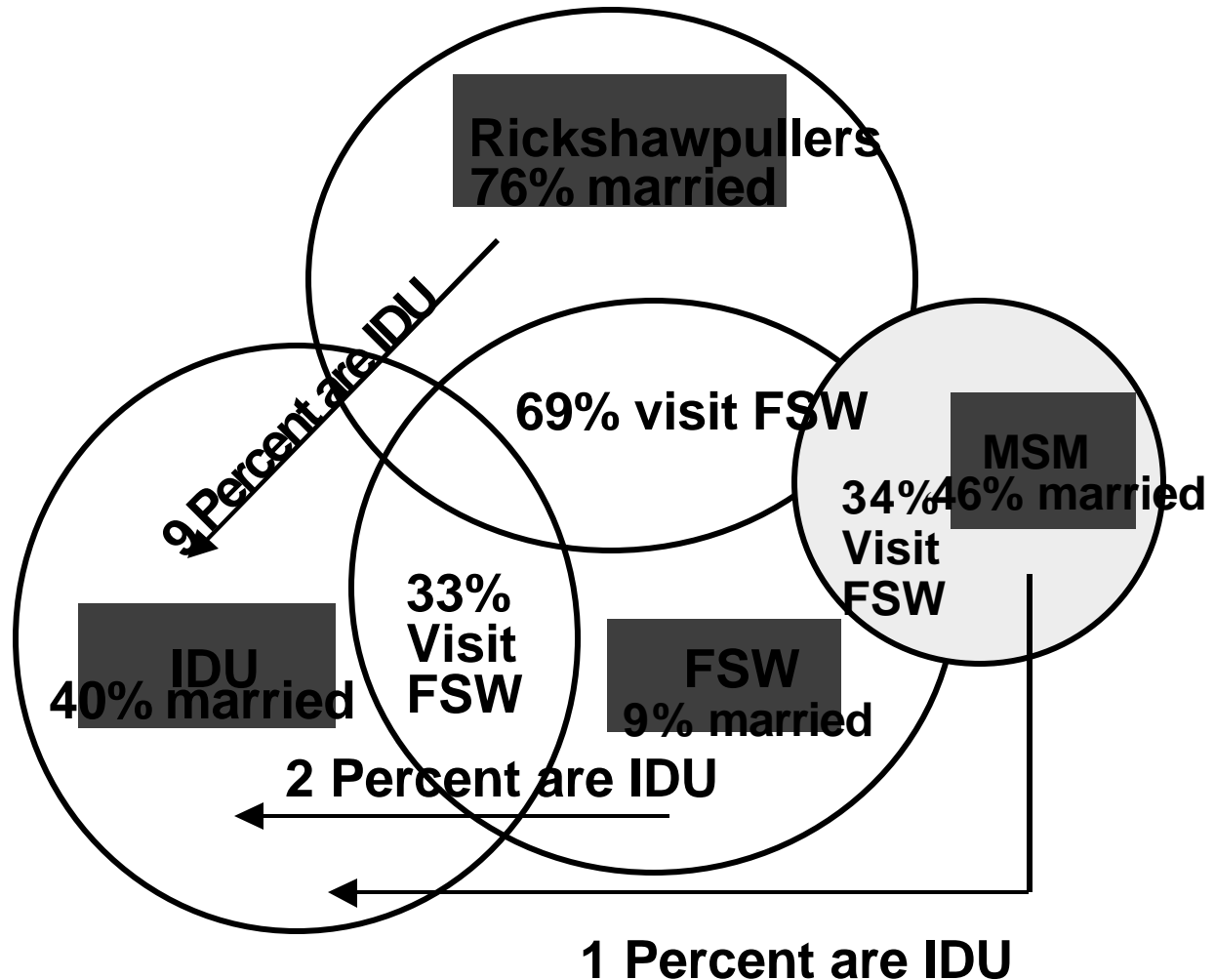
SEXUAL PARTNERS OF MSM IN CAMBODIA



MSM HAVING SEX WITH WOMEN IN ASIA



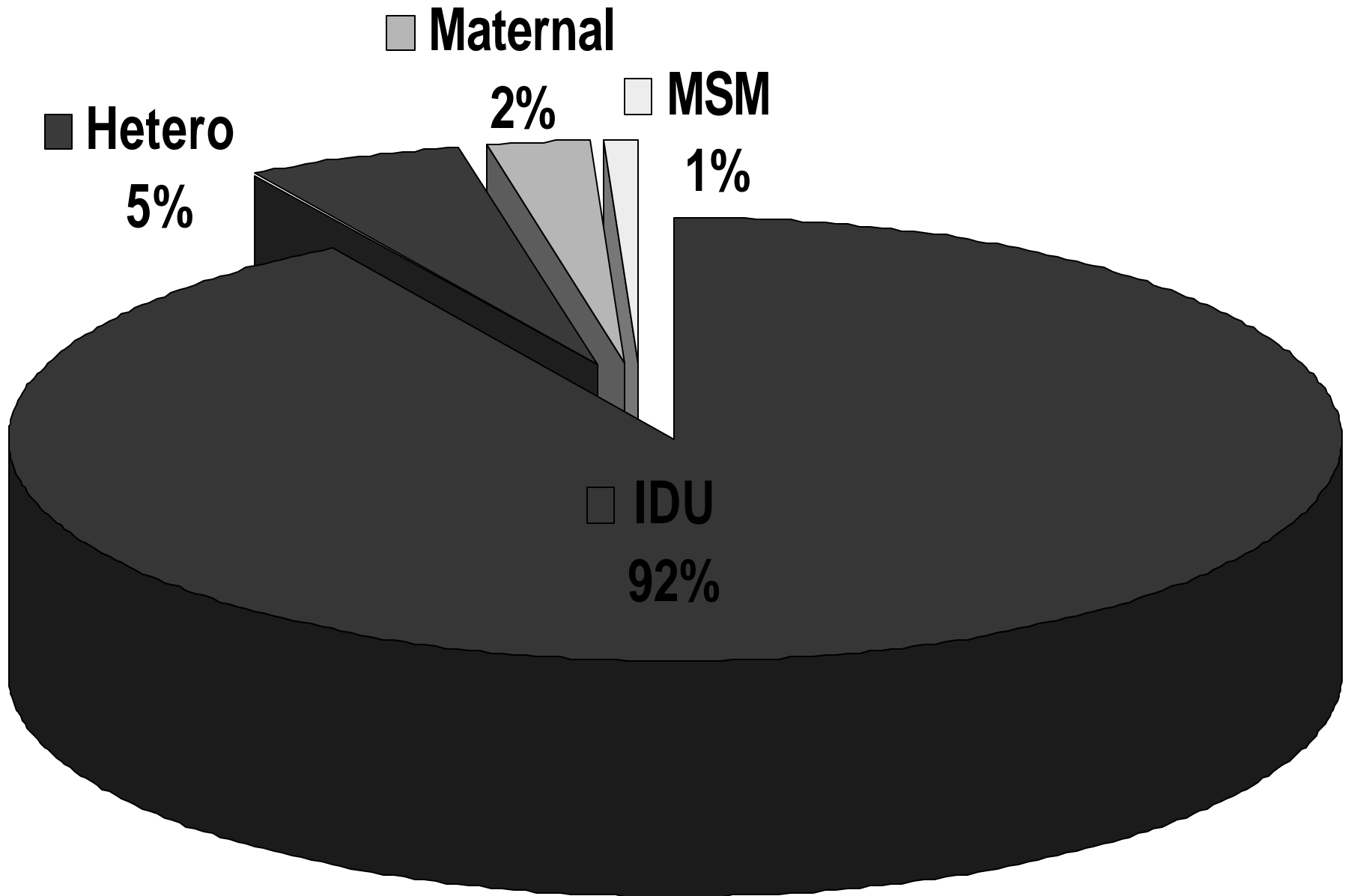
INTERACTIONS IN BANGLADESH



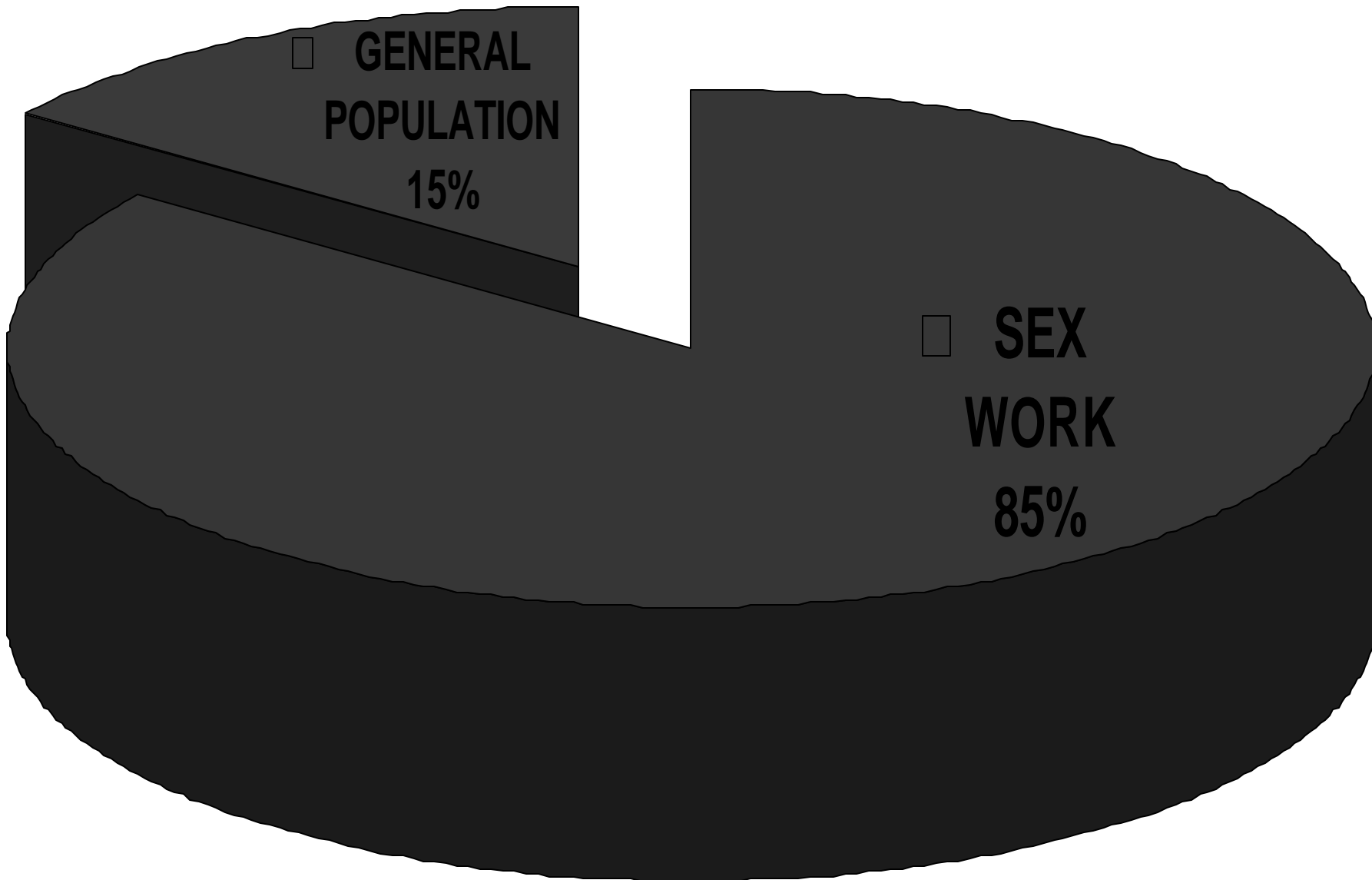
ESTIMATED PROPORTION OF INFECTIONS (1)

- The next step is to estimate the proportion of infections attributable to different forms of exposure**
- This is vital to ensure effort and resources reflect transmission dynamics**

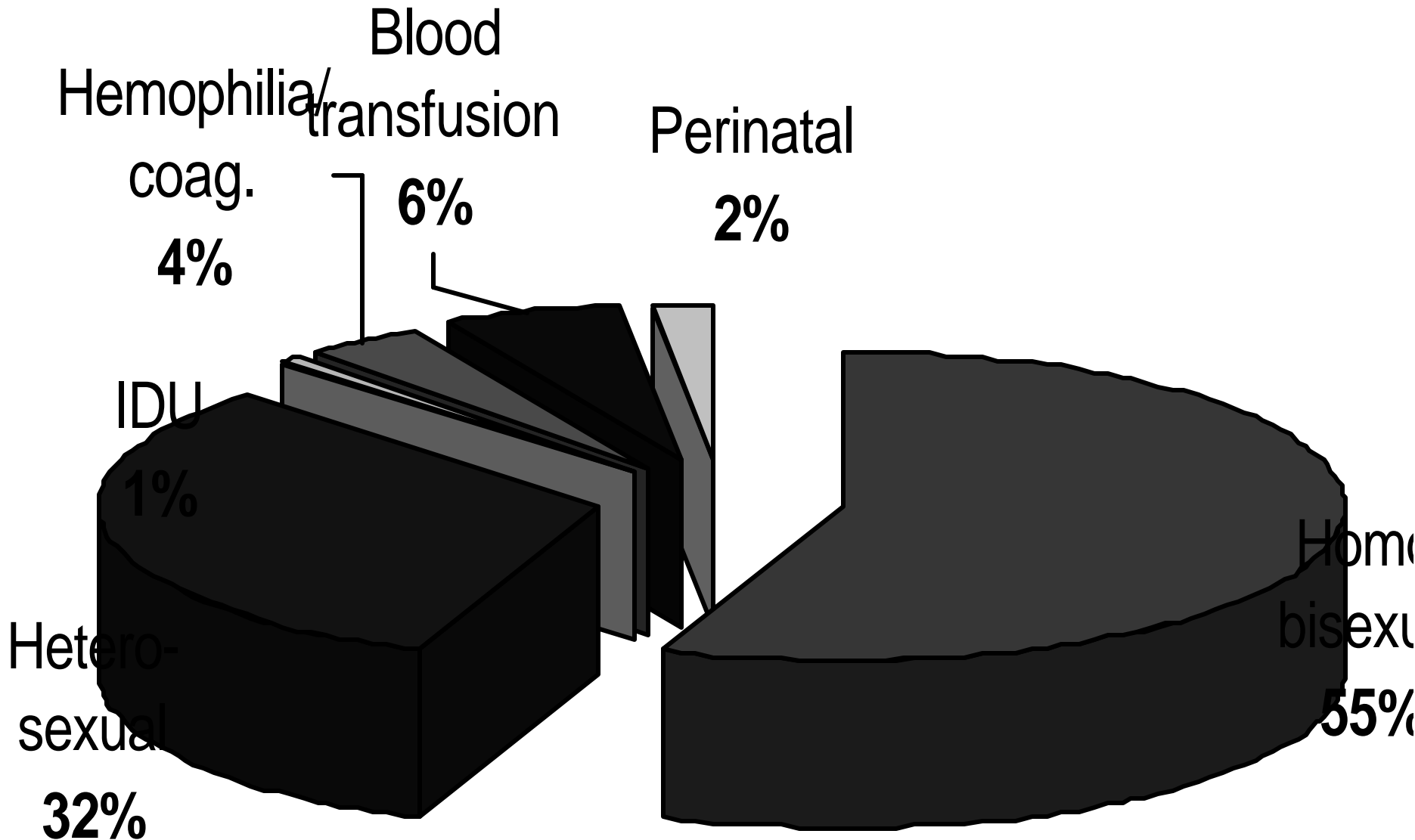
HIV INFECTION IN RUSSIA



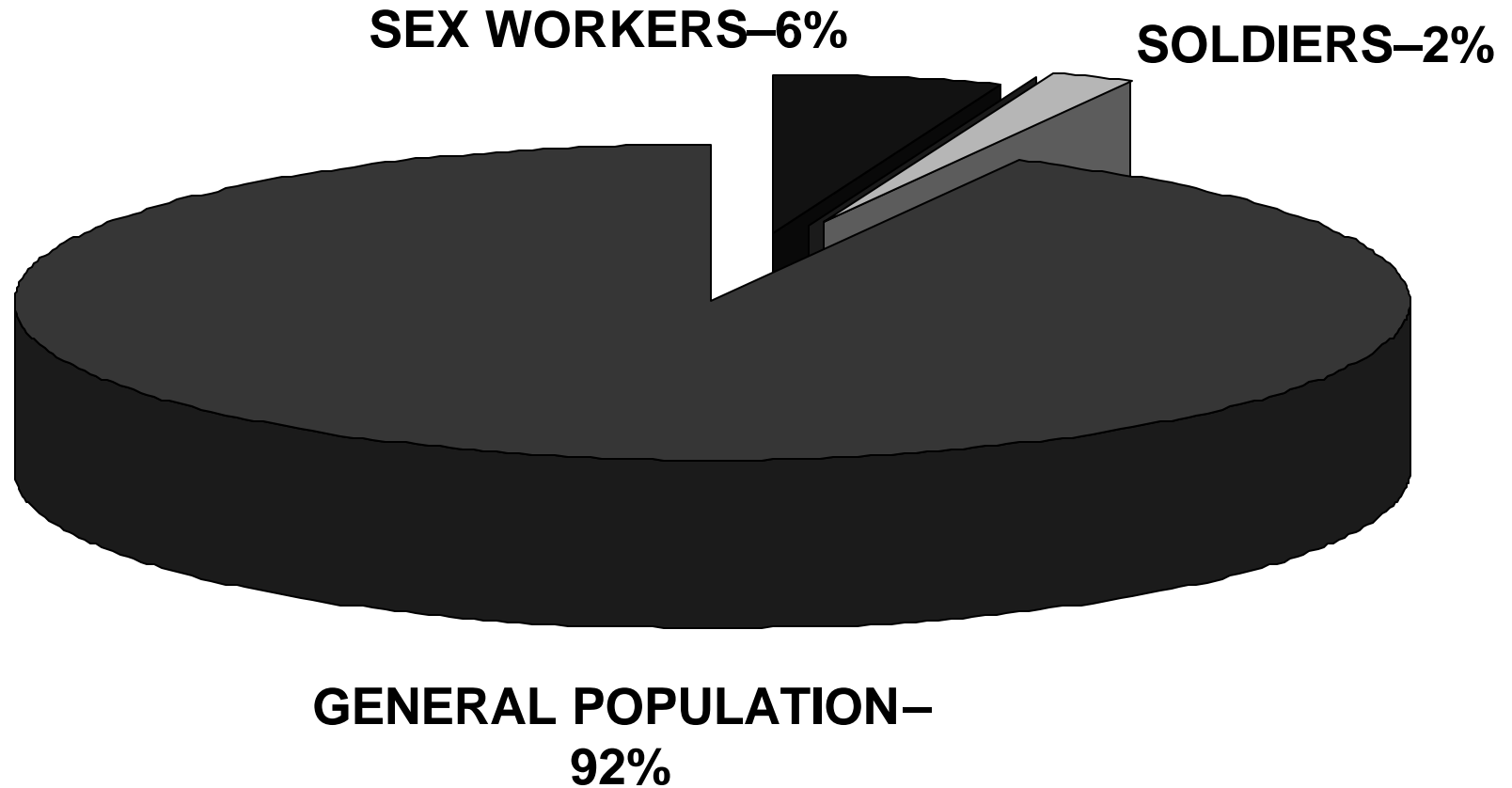
HIV INFECTION IN GHANA



HIV INFECTION IN MEXICO



HIV INFECTION IN ZAMBIA



ESTIMATED PROPORTION OF INFECTIONS (2)

□ How do we estimate proportion of infections from different sources?

Intuitive

□ If HIV prevalence is 80% among sex workers and 1% in the general population, we can deduce sex work is the major source of HIV infection

ESTIMATED PROPORTION OF INFECTIONS (3)

Delphi

□ We ask experts for estimates – for example, Lebanese infectious disease physicians report heterosexually transmitted HIV acquired by travelers to high prevalence countries

ESTIMATED PROPORTION OF INFECTIONS (4)

Risk factor studies

□ The simplest way is to ask HIV-positive people their risk factors and classify accordingly

□ More complex risk factor studies use multiple regression on HIV status to estimate effect sizes for different risk factors

ESTIMATED PROPORTION OF INFECTIONS (5)

Population attributable fraction (PAF) studies

□ PAF studies estimate the fraction of infections attributable to different sources, using epidemiological and behavioral data

□ For example, recent PAF study in Accra, Ghana concluded 76% of adult male infections attributable to sex work

□ In contrast, similar Zimbabwean and Zambian studies suggest 1-9%

ESTIMATED PROPORTION OF INFECTIONS (6)

Computer models

□ There are several computer models to estimate the proportion of infections from different sources, including the Asian Epidemic Model (AEM) and LSHTM's HIVTOOLS

ESTIMATED PROPORTION OF INFECTIONS (7)

Molecular epidemiology

□ Molecular epidemiology uses genetic characterization of HIV to assign subtypes and calculate relatedness between isolates

□ For example, over 90% of HIV-positive Vietnamese IDU in Melbourne, Australia acquired HIV while injecting during visits to Vietnam

□ Other studies show clear viral overlap between IDU and SW in Denpasar, Bali

FROM PROBLEM TO RESPONSE (1)

□ Having assessed the problem in previous steps, we now assess the response in the following steps

PROGRAM SERVICES (1)

□ Program monitoring is the first essential step in monitoring the HIV response. For example:

□ Injecting drug user programs promote safe injecting equipment and practices, condom use and drug substitution therapy

□ Sex worker programs promote improved sexual health, condom use, solidarity and group empowerment and legislative and policy reform

□ MSM programs promote safe sexual practices and legislative and policy reform

PREVENTION PROGRAM FOR IDU IN UKRAINE

Minimum package

- Personal protective equipment (syringes, condoms)
- Information materials
- Outreach and prevention counseling

Larger package

- Above, plus
- HIV counseling and testing
- Specialist counseling
- Referrals to STI/hepatitis diagnosis/treatment)
- Referral to programs for drug addiction
- Referral to substitution therapy programs
- Self-help groups

PROGRAM SERVICES (2)

- Regular program monitoring, using structured reporting forms, by service providers, is particularly important in smaller countries, with low HIV prevalence rates and limited numbers of providers**
- In larger countries with greater prevalence, program monitoring has a role, but the emphasis on structural rather than individual interventions, particularly in larger countries with higher prevalence, poses challenges**
- Examples of structural interventions include legislating 100% condom use in sex establishments, socially marketing condoms in red light districts or providing free or subsidized needles through retail outlets**
- Structural interventions may require surveys as well as program reporting**

COVERAGE (1)

- Coverage is a critical measure of program performance and a prerequisite for risk reduction
- How do we estimate coverage?

COVERAGE (2)

Program monitoring

□ If we have an estimated 1,000 IDU in a city and our program monitoring records show we have enrolled 500, our estimated coverage is 50%

COVERAGE (3)

Service statistics

Advantages

- Does not require special survey

Disadvantages

- No real denominator
- Limited accuracy
- Hard to prevent double-counts

COVERAGE (4)

Behavioral surveys – coverage items

□ We can – and should - include items on program coverage, including exposure to different intervention components and frequency of exposure in behavioral surveys

COVERAGE (5)

Behavioral surveys – coverage items

Advantages

- ❑ Produces more accurate coverage estimates
- ❑ May be included in existing behavioral surveys

Disadvantages

- ❑ Requires survey
- ❑ Requires effective sampling strategy, especially with hidden populations

COVERAGE (6)

- Achieving coverage vital – but difficult**
- UNAIDS estimate coverage of vulnerable populations in concentrated epidemics is under 10%**

OUTCOMES (1)

□The key outcomes in concentrated epidemics are reduced unsafe sexual and injecting practices

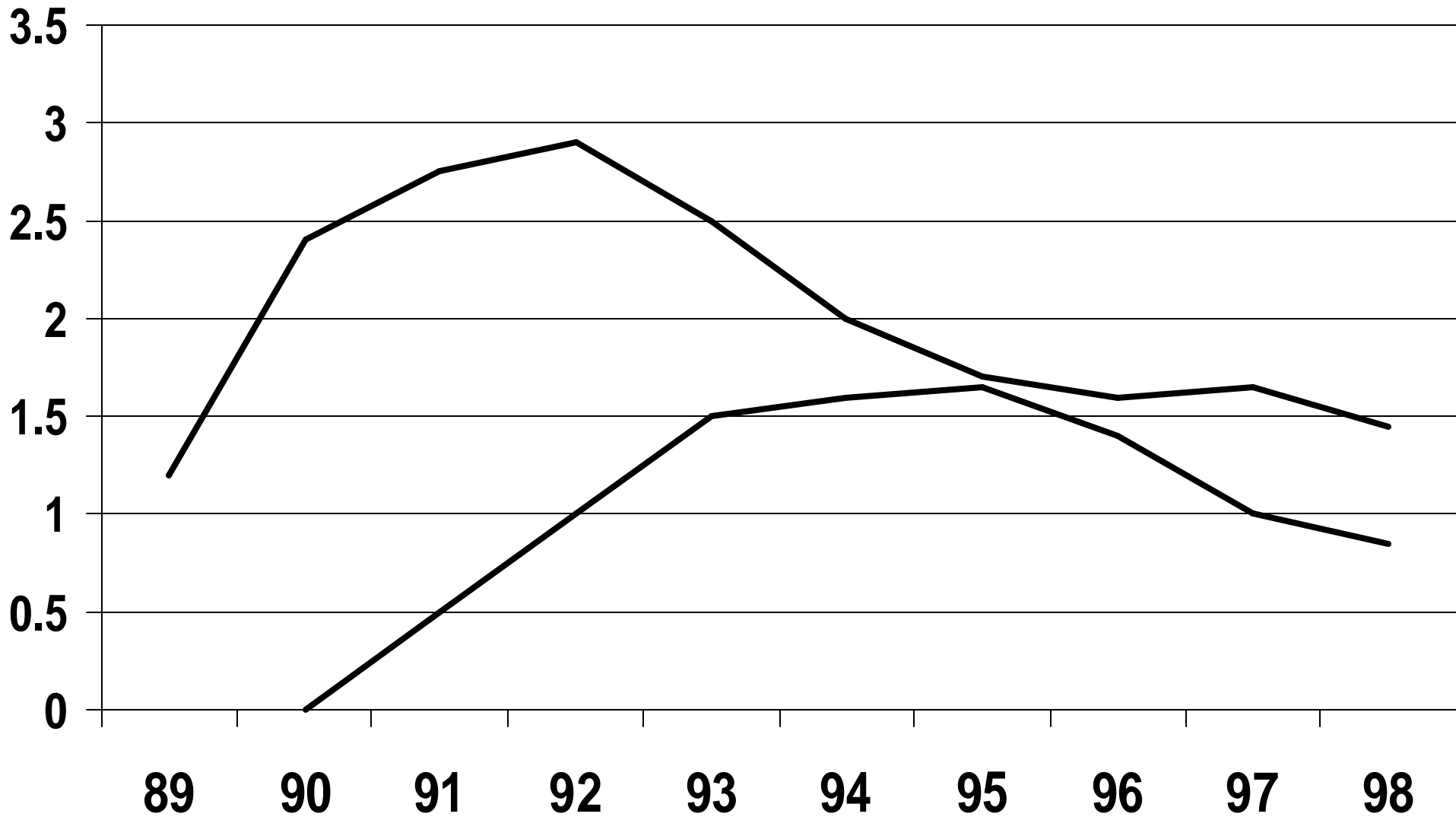
□We measure outcomes using behavioral surveys

IMPACTS (1)

- The key impacts in concentrated epidemics are reduced HIV transmission and AIDS morbidity and mortality**
- We measure impacts using HIV prevalence surveys and AIDS clinical records**

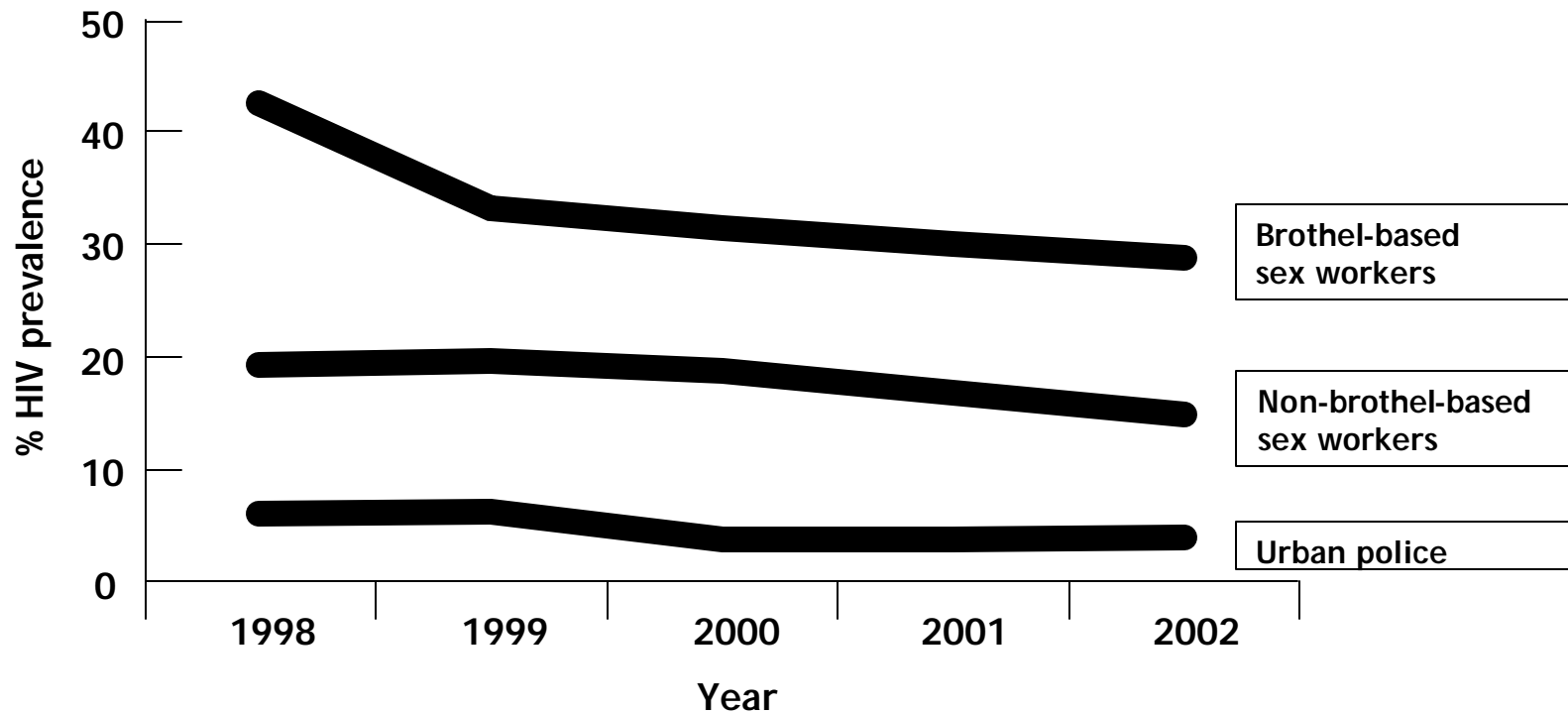
HIV PREVALENCE IN THAILAND

— ANC — CONSCRIPTS



Sources: Peerapatanapokin et al, 2004

HIV PREVALENCE IN CAMBODIA



CONCLUSIONS (1)

THE PRIMACY OF SECONDARY PREVENTION

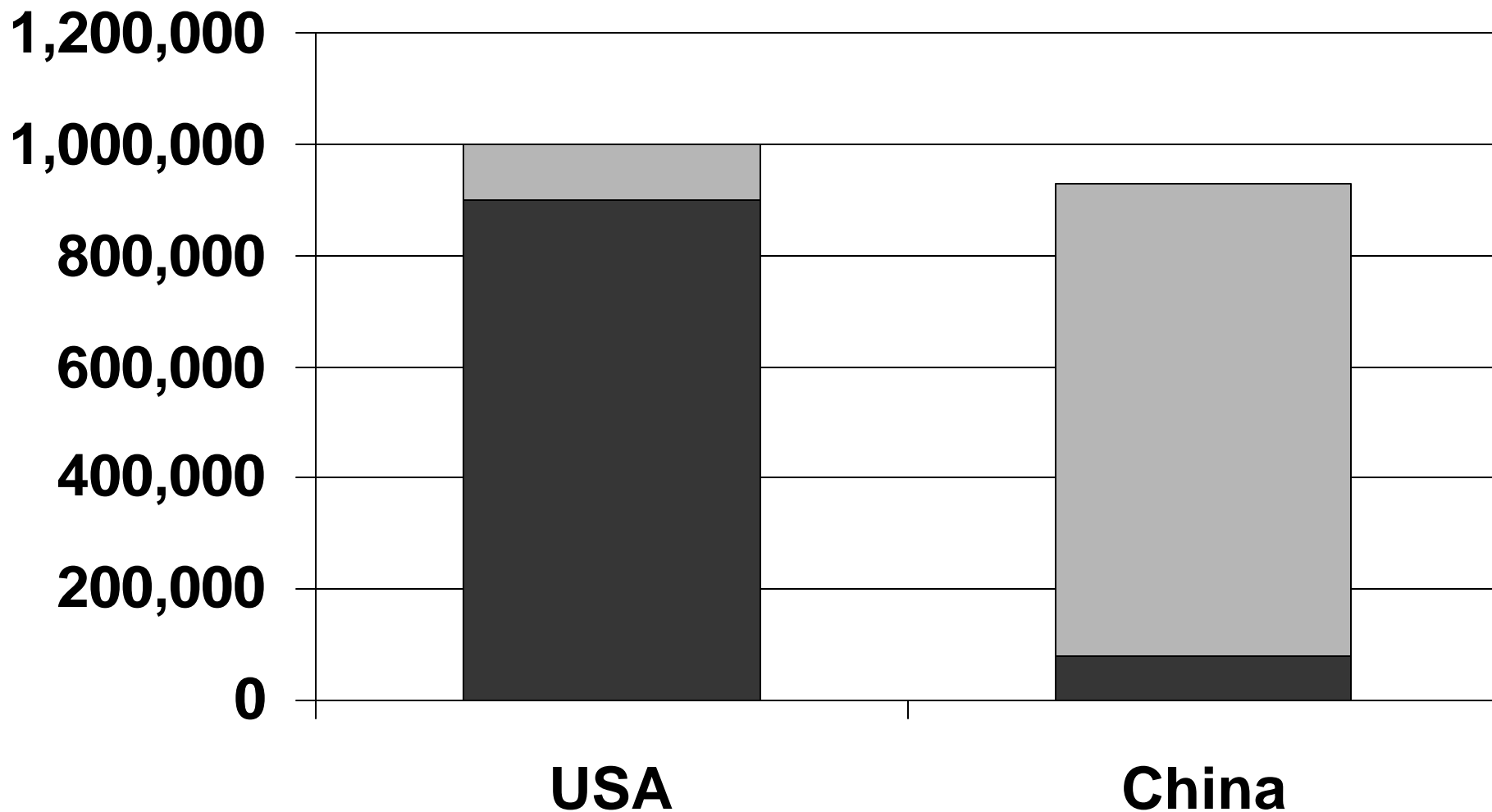
□ Primary prevention focuses mainly on the uninfected and secondary prevention focuses mainly on the infected

□ Monitoring and evaluation focuses mainly on primary prevention in generalized epidemics and on secondary prevention in concentrated epidemics

□ This creates invaluable opportunities for intensive, integrated prevention, treatment and support in the context of secondary prevention, as this simple example shows

SECONDARY HIV PREVENTION: THE DIFFERENCE BETWEEN USA AND CHINA

■ Know HIV Status ■ Don't Know HIV Status



CONCLUSIONS (2)

THE LOGIC OF CONCENTRATED EPIDEMICS

□ Concentrated epidemics require a particular logic, in which we progressively estimate HIV prevalence, population size and interactions to assess the problem, then assess program services, coverage, outcomes and impacts, to assess the response

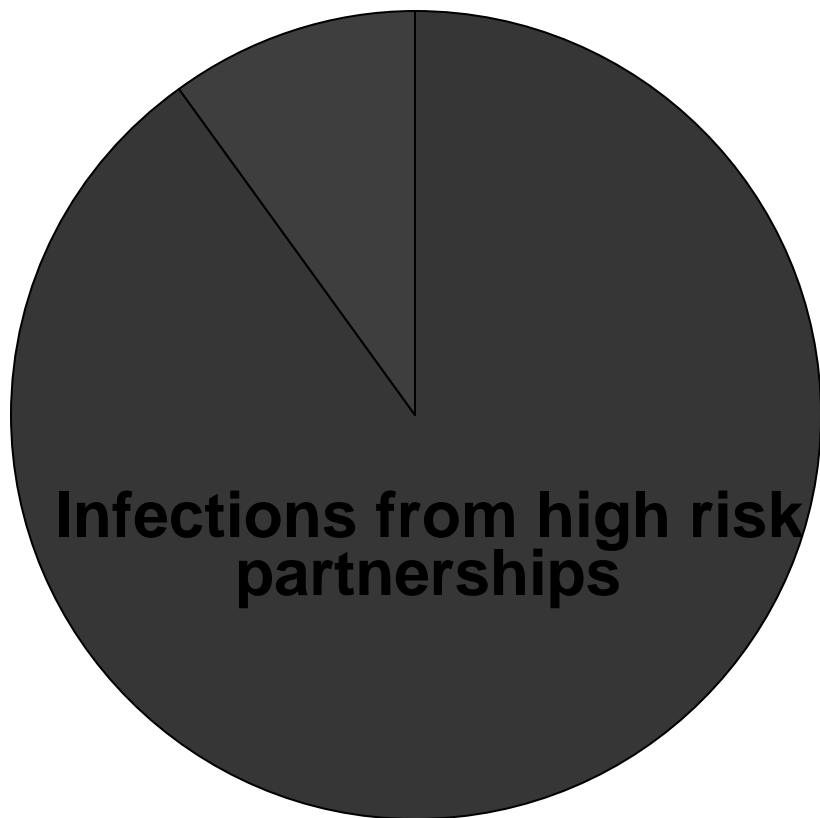
□ Concentrated epidemics are preventable – we have the knowledge and M&E tools to stem transmission

CONCLUSIONS (3)

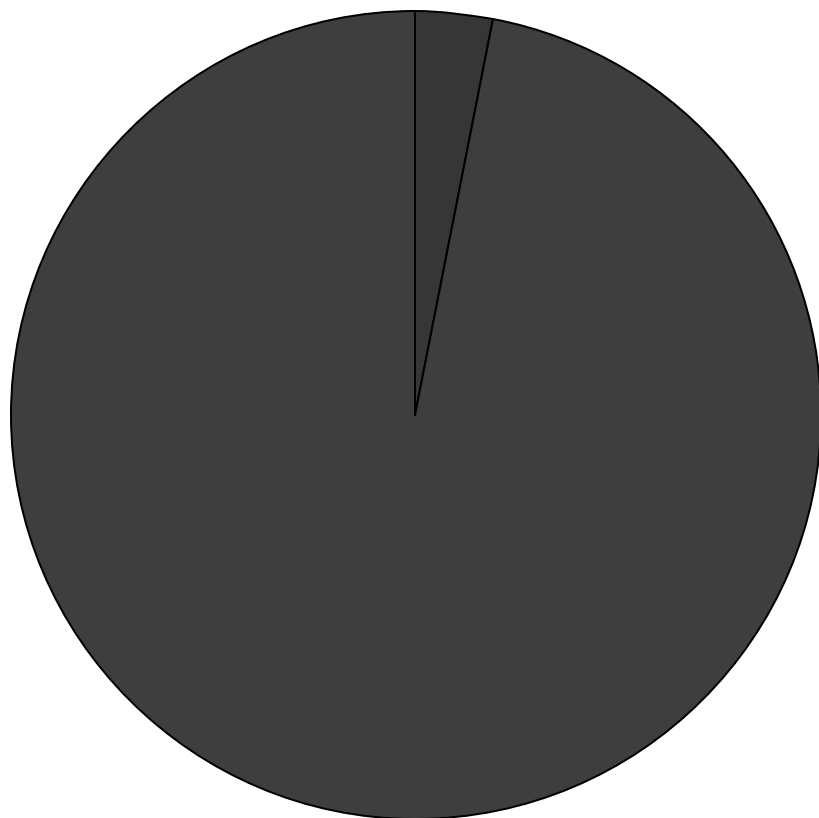
DO THE RIGHT THING, DO IT RIGHT, DO ENOUGH OF IT

Are we doing the right thing?

HIV TRANSMISSION AND PREVENTION PRIORITIES IN GHANA



Resources for high risk interventions

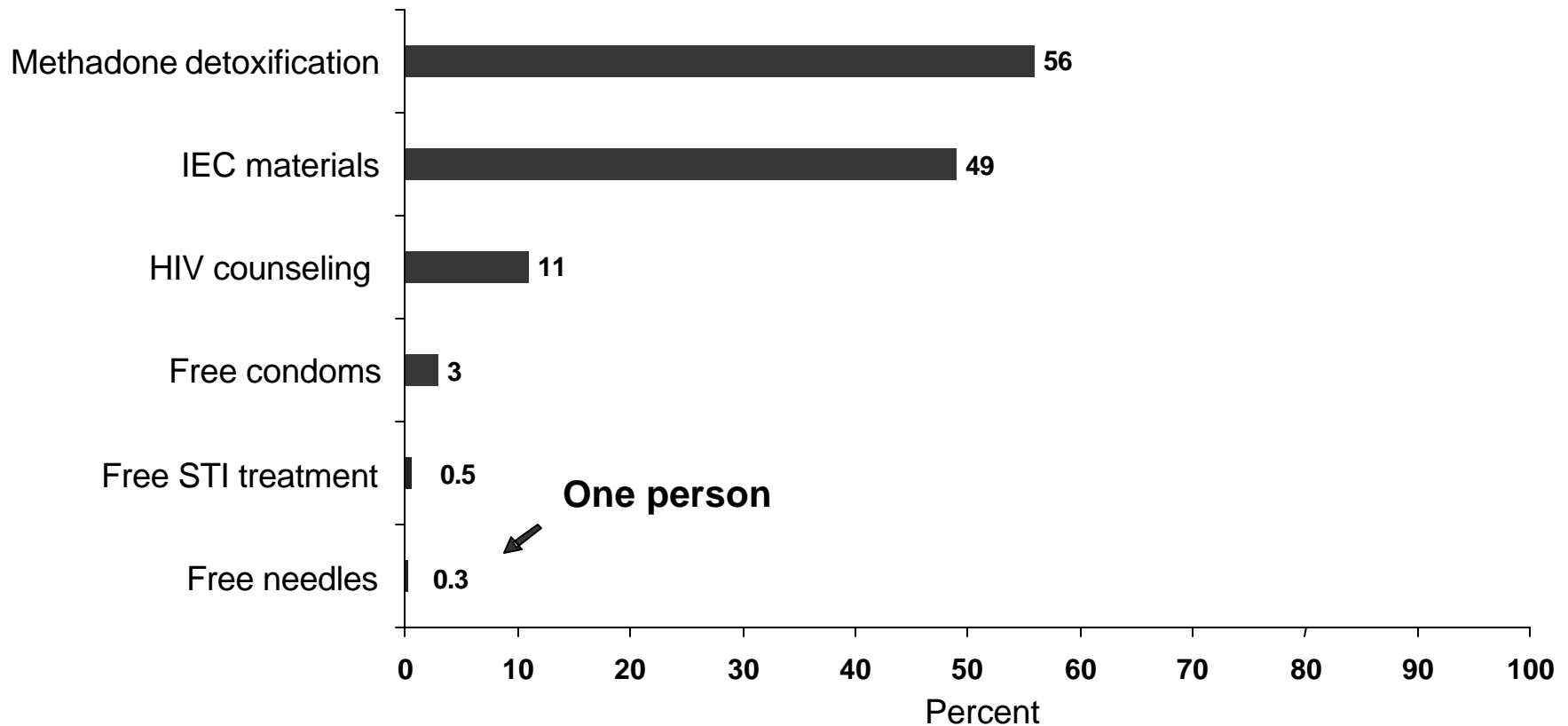


CONCLUSIONS (4)

DO THE RIGHT THING, DO IT RIGHT, DO ENOUGH OF IT

Are we doing it right?

IDU IN YUNNAN, CHINA CAN'T INJECT SAFELY WITH A PAMPHLET

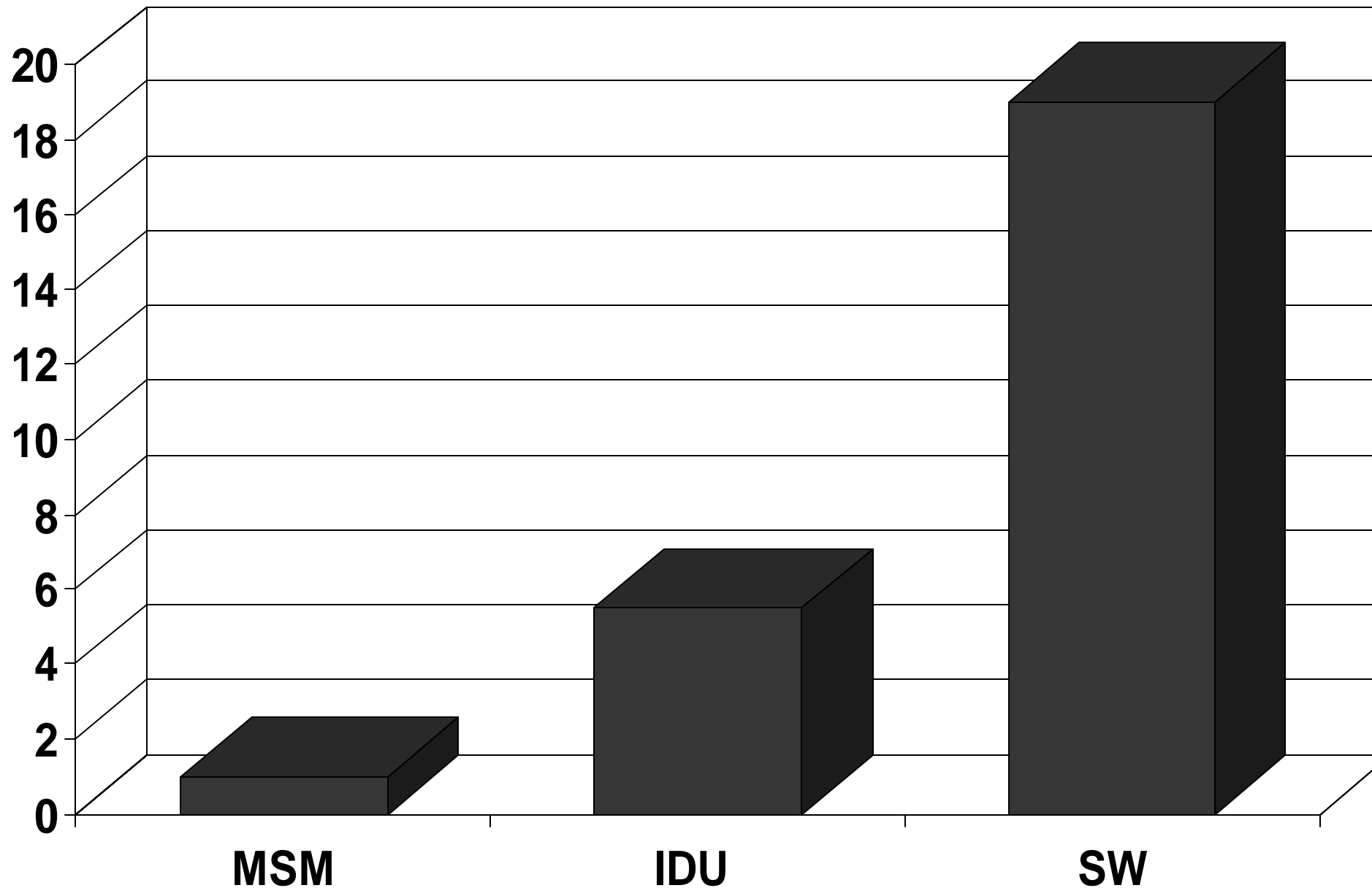


CONCLUSIONS (5)

DO THE RIGHT THING, DO IT RIGHT, DO ENOUGH OF IT

Are we doing enough of it?

COVERAGE OF VULNERABLE GROUPS IN ASIA



Sources: UNAIDS, 2005

CONCLUSIONS (6)

MONITORING AND EVALUATION IS CENTRAL

- 1. Understand, but don't overcomplicate. Delineate and address major drivers of transmission**
- 2. Have courage to recognize transmission is primarily among vulnerable groups and to protect them**
- 3. Ensure vulnerable group prevention funding is broadly commensurate with proportion of infections attributable to vulnerable groups**
- 4. Identify best proven approaches for context and key determinants of success**
- 5. Identify all sites with many vulnerable group members**
- 6. Enumerate the size of vulnerable groups in each site**
- 7. Routinely track coverage, to ensure all/most vulnerable group members are reached**
- 8. Routinely track quality, to ensure key determinants of success are delivered**
- 9. Selectively assess biological impact, to ensure approaches remain effective and for advocacy**