KESINAMBUNGAN PENGOBATAN ANTIRETROVIRAL DI INDONESIA

DISAMPAIKAN OLEH: DYAH ERTI MUSTIKAWATI – KASUBDIT AIDS & PMS DALAM SIMPOSIOUM KESINAMBUNGAN ART UNIKA ATMAJAYA – 20 April 2009

Direktorat Jenderal PP & PL Departemen Kesehatan R I
COUNTRY BACKGROUND

Country Background

- The fourth largest population country with estimated population 237,512,352.
- 33 Provinces and more than 400 Districts.
- More than 17,508 islands. Communication and distribution challenges are huge problem in any aspect.
- GDP per capita (2007) $ 1,953 (115th)
- 1987: The MoH established “Pokja Penanggulangan HIV/AIDS”, 1994 (Perpres 36) government established NAC under the Coordinating Minister of People Welfare → July 2006 re-organize under the President Decree 75
Number of AIDS Cases Reported in Indonesia in Last 10 Years up to March 31, 2009

<table>
<thead>
<tr>
<th>Year</th>
<th>AIDS</th>
<th>Kumulatif</th>
</tr>
</thead>
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<td>255</td>
<td>255</td>
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<tr>
<td>2001</td>
<td>607</td>
<td>862</td>
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<tr>
<td>2002</td>
<td>219</td>
<td>1081</td>
</tr>
<tr>
<td>2003</td>
<td>826</td>
<td>1907</td>
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<tr>
<td>2004</td>
<td>345</td>
<td>2252</td>
</tr>
<tr>
<td>2005</td>
<td>1171</td>
<td>3423</td>
</tr>
<tr>
<td>2006</td>
<td>1487</td>
<td>4910</td>
</tr>
<tr>
<td>2007</td>
<td>1195</td>
<td>6105</td>
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<td>2639</td>
<td>8744</td>
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<td>1195</td>
<td>10939</td>
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<td>2010</td>
<td>2639</td>
<td>13578</td>
</tr>
<tr>
<td>2011</td>
<td>854</td>
<td>16110</td>
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</table>
10 Provinces in Indonesia With Highest AIDS Cases up to March 31, 2009

- Jawa Barat: 3162
- DKI Jakarta: 2807
- Jawa Timur: 2652
- Papua: 2499
- Bali: 1263
- Kalimantan Barat: 730
- Jawa Tengah: 573
- Sumatera Utara: 485
- Riau: 368
- Kepulauan Riau: 325

AIDS
# Kecenderungan Epidemi Perevalensi HIV diantara usia dewasa (15-49) dan remaja (15-24), 2001-2007

<table>
<thead>
<tr>
<th>Year</th>
<th>Adults 15-49 (Female)</th>
<th>Adults 15-49 (Male)</th>
<th>Young people 15-24 (2007) (Male)</th>
<th>Total</th>
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<td>0.1</td>
<td>0.1</td>
<td>0.2</td>
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<tr>
<td>2005</td>
<td>0.1</td>
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<td>2007</td>
<td>0.2</td>
<td>0.3</td>
<td>0.3</td>
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Source: 1. Indonesia_UNAIDS, Epidemiological Fact Sheets, 2008 Update  
Peningkatan Program Pencegahan
Persentase populasi berisiko yang dijangkau oleh program pencegahan berdasarkan kelompok umur, 2007

FSWs
MSM
IDUs

<25 25+ All

Source: UNAIDS, UNGASS Country Report Indonesia January 2006 to December 2007
Comprehensive knowledge of HIV&AIDS: Percentage of people who both correctly identify ways of preventing the sexual transmission of HIV and who reject major misconceptions (UNGASS definition)

Source: 1. UNAIDS, UNGASS Country Report Indonesia January 2006 to December 2007
• RESPONS TERHADAP EPIDEMI HIV – SITUASI PENGOBATAN

1. Status peningkatan layanan ART
Jumlah layanan PDP di tahun 2008

Total ART services in Indonesia are 148 Hospital, 122 are referral Hospital and 26 are satellites
(Update April 2008)
2. Status peningkatan layanan VCT
Sebaran Layanan VCT di Indonesia

General
CHC
Mental Hospital
NGO
Prison

ESTABLISHED IN 123 DISTRICTS OUT OF 440 DISTRICTS
Persentase dewasa dan anak % of adults and children with advanced HIV infection receiving ART, 2007

Source: UNAIDS, UNGASS Country Report Indonesia January 2006 to December 2007
Layanan konseling dan testing meningkat dari 25 unit pada tahun 2004 menjadi 482 pada tahun 2008
Masuk Perawatan HIV
Memenuhi Syarat ART
Pernah Menerima ART
Masih Menerima ART

Oktober 2008
Hasil Pengobatan ARV – Maret 2009

Masuk perawatan HIV = 38.888

Memenuhi syarat untuk ART = 25.575 (65,77%)

Pernah menerima ART = 19.579 (76,56%)

Meninggal = 3.716 (18,98%)

Masih menerima ART = 11.834 (60,44%)

Orisinal lini 1 = 9.422 (79,61%)

Substitusi = 2.208 (18,66%)

switch = 204 (1,72%)

Belum syarat ART = 13.313

Belum mulai ART = 5.996

Lost follow-up = 2.163
Transfer Out = 1.134
Stop = 732

18,98%
Dampak ARV

- % of ART eligible PLHA
- % of PLHA ever treated ARV
- % of PLHA currently on ART
- % of Death after treatment
Government Policy

- Free of charge for ARV drugs (Ministry of Health regulation No 83 2004)
- Should strictly follow the guidelines regarding:
  - Start, Substitute, Switch and Stop the ART
  - First line and 2nd line
  - Each health facility should maintain the 3 month stock of ARV
- The government will gradually shift the ARV distribution authority to Provincial Health Office after they are assessed their preparedness
• SUPPLY CHAIN MANAGEMENT

Definition

- **Supply chain** means all the activities between manufacture of a drug or products and the ultimate delivery to the patient.

- **Lead time** is the time taken from placement of order until receipt of the drugs.

- **Dispensing** means the full process of prescription review, selection of drugs/product, labelling of drugs/product, checking of product, counselling of patient, supply of drug to the patient.

- **Uninterrupted supply** means continuously supply of drugs/product without being stock out.
Questions

- Why are limited stock / stock out of drugs or reagen repeatedly being reported in some hospitals?
- What are the problems in Communication Mechanisms?
- What are the problems in reporting & ordering of supplies?
- Is lead time a problem for distribution of ARV drugs or reagen or another product to facility?
Reasons to prevent stock out ARV

- A continued and uninterrupted drug supply of ARV is essential to avoid the development of HIV Drug Resistance.
- The stock-out of drugs is one of the indicators of early warning system for ARV drug resistance.
- Limited alternatives when there are stock-outs.
Ensure uninterrupted supply

Monitoring Evaluation

Selection

Procurement

Use

Management support
Management information system

Technical selection
Planning & forecasting
Policy: Compulsory license

Storage and Distribution

Tender & Bidding
Order to manufacturer
Or Import
Customs clearance

Use

Treatment protocols
Prescription practice
Dispensing

Management information system

Monitoring Evaluation

Selection

Procurement

Use

Management support
Management information system

Technical selection
Planning & forecasting
Policy: Compulsory license

Storage and Distribution

Tender & Bidding
Order to manufacturer
Or Import
Customs clearance

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Management information system

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Customs clearance

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Monitoring Evaluation

Selection

Procurement

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Management support
Management information system

Technical selection
Planning & forecasting
Policy: Compulsory license

Storage and Distribution

Tender & Bidding
Order to manufacturer
Or Import
Customs clearance
The Current ARV Distribution System

SUBDIT AIDS (NAP) → Delivery Order → PT Kimia Farma or GF Logistic

Cc Delivery Order

Prov. Health Office

Warehousing: - Stock - Buffer

Logistic Report

Report and Request Letter

ART Hospital → ARV Delivery

Referral and Mentoring

ART Hospital

Satellite ART Hospital → Referral and Request for ARV

Monitoring and evaluation

Referral

Primary Health Center

Referral and Monitoring
The Future ARV Distribution System (?)

SUBDIT AIDS (NAP)

- Cc Delivery Order
- Report and Request Letter

Distric Health Office

- Monitoring and evaluation
- Referral and Request for ARV

Prov. Health Office

- Report and Request Letter
- ARV Delivery every month

WAREHOUSE:
- Stock 6 month
- Buffer
- Relocation

PT Kimia Farma or GF Logistic

- Logistic Report
- ARV Delivery every 3 month
- Minimal stock in central level 6 month

ART Hospital

- Minimum stock 2 weeks in patient

Satelite ART Hospital

Primary Health Center

Referral
The Future ARV Distribution System

KF

Warehouse

Foreign ARV Manufacturers

Custom Clearance

Port to Warehouse Transport

Receiving – Storage – Despatch

Delivery / Transport

Scope of Work

Not in scope of work

Slide from CF
National Commitment and Action

Sources of Fund: Public Vs. International

Proportion of AIDS Spending by Sources of Fund in 2006

- Public: 75.76%
- International: 24.24%

Unless Government put more attention to priority programs such as AIDS, Dependency to external sources remain.
**HIV Treatment Challenges**

- Treatment for HIV/AIDS is available in the form of anti-retroviral drugs.
- These can prolong lifespan and dramatically improve the health of people living with HIV/AIDS.
- Problems: cost, access & distribution, ability to manufacture own generic drugs, drug resistance.

**Benefits of ARV Therapy**

- Prevents opportunistic infections
- Alters/reverses course of existing opportunistic infections
- Decreases hospitalizations

- Increases survival
- Improves quality of life
- Restores hope
- Reduces HIV transmission
- Benefits both adults and children

**ARVs change HIV from a terminal (fatal) disease to a “chronic disease”**.
Clinically licensed anti-AIDS agents

- **Entry I**: enfuvitirde
- **NRTIs**: zidovudine, didanosine, zalcitabine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine
- **NNRTIs**: nevirapine, delavirdine, efavirenz
- **PIs**: saquinavir, indinavir, nelfinavir, amprenavir, lopinavir, ritonavir, atazanavir, fosamprenavir
- **Integ.I.**: raltegravir
INDONESIA

- **1st line**: Zidovudine, Stavudine, Lamivudine, Nevirapine, Efavirenz
- **2nd line**: Lopinavir/ritonavir, Tenovofir, Didanosine

On Planning: Abacavir, Emtricitabine
Infeksi oportunistik yang terbanyak dilaporkan sampai 31 Maret 2009

- TBC : 9493
- Diare kronis : 4993
- Kandidiasis oro-faringeal : 4897
- Dermatitis generalisata : 1298
- Limfadenopati generalisata persisten : 629
ARVs price list by Kimia Farma
(5 Februari 2009)

- Harga ARV cenderung menurun

- 1st line: 247.940 – 462.440
  rata-rata sekitar 350.000/bln
  Rp. 4.200.000 per tahun/per orang

- 2nd line: 1.360.000 – 1.687.000
  rata-rata sekitar 1.500.000/bln
  Rp. 20.000.000 per tahun/orang

Note pendapatan perkapita $1,925
### Stok ARV 15 Januari 2009

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<th>NO</th>
<th>ARV</th>
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<th>TOTAL STOK</th>
<th>PREDIKSI KECUKUPAN (BLN)</th>
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<td></td>
<td></td>
<td>KF</td>
<td>GF</td>
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<td>4</td>
<td>D4T</td>
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<td>1</td>
<td>Duviral (3TC+AZT)</td>
<td>5165 btl</td>
<td>7500</td>
<td>Negatif</td>
<td>1. PL 01.01/III.2/367/2009 tgl 2 Maret 2009 4000 btl</td>
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<tr>
<td></td>
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<td>+ (-7000)</td>
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<td></td>
<td>2. Tgl 7 april 2009 pinjam 14000 btl. Tg 16/4/09 Realisasi 7000. sisa stok 1200 btl</td>
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<td>2</td>
<td>Avocomb (3TC+AZT)</td>
<td>10000</td>
<td>7500</td>
<td>1.3 bulan</td>
<td>Total Stok (3TC+AZT) 11.200 botol cukup 1.5 bulan</td>
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<td>Staviral (d4T)</td>
<td>3827 btl</td>
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<td>+ (-3500)</td>
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<td>Coviro (d4T+3TC)</td>
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<td>Nevilast (d4T+3TC+NVP)</td>
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<td>Neviral</td>
<td>1173 btl</td>
<td>6400</td>
<td>Negatif</td>
<td>1. Tgl 7 april 2009 pinjam 13000 btl. Tg 16/4/09 Realisasi 6500. sisa stok 1200 btl</td>
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<td>7</td>
<td>Nevirapine</td>
<td>10000</td>
<td>6400</td>
<td>1.5 bulan</td>
<td>Total Stok (NVP) 12.569 btl cukup 2 bulan</td>
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## Stok ARV 20 April 2009 (2)

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<td>3TC dalam Bentuk kombinasi</td>
<td>11319</td>
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<td>Efavirenz</td>
<td>8593 btl</td>
<td>4300</td>
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<tr>
<td>11</td>
<td>Efavirenz dari GF</td>
<td>21699</td>
<td>4300</td>
<td>5 bulan</td>
<td>Total Stok (EFV) 30.292 cukup 7 bulan</td>
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<td>12</td>
<td>Didanosine</td>
<td>1271 btl</td>
<td>200</td>
<td>6 bulan</td>
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<td>13</td>
<td>Didanosine Dari GF</td>
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<td>200</td>
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<td>Total Stok (ddI) 1597 btl, cukup 7.5 bulan</td>
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<td>5.2 bulan</td>
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<tr>
<td>1</td>
<td>LPV+RTV 200+50mg</td>
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<td>LPV+RTV 200+50mg</td>
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<tr>
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<tr>
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<td>3/30/2009</td>
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<td>Efavirenz</td>
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<td>14</td>
<td>Tenofovir</td>
<td>1078</td>
<td>5/4/2009</td>
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<tr>
<td>16</td>
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ANTISIPASI KEDEPAN

- GF: Untuk procurement ARV dari pendanaan GF selanjutnya (R-4 tahun 2009) menggunakan program VVP dari Global Fund dan untuk clearance, warehousing dan in-country distribution bekerjasama dengan PT Kimia Farma.

- APBN: Diupayakan agar pelaksanaan pengadaan ARV segera dilaksanakan, jika memungkinkan agar pengadaan kebutuhan obat ARV dilaksanakan secara terpisah tanpa harus menunggu pengadaan obat program dari Unit di Departemen Kesehatan lainnya.
ARV stock out?

- ARV supply at extreme risk, requiring to seek emergency assistance. First, the national budget allocation for ARVs in 2008 was cut by 50% from what was required to supply Indonesia for the year.

- The national budget is primarily used to buy drugs for patients on first-line regimens.

- In 2008 attempted for the first time to conduct a competitive bid for 2008 allocation from the Global Fund. Unfortunately, this transition was not smooth and experienced unexpected difficulties and delays, which led to the ultimate failure of the tender.
ARV stock out? (2)

- Upon the failure of the tender, the direction from the Minister of Health was to pursue the procurement path with the Ministry of Health’s pharmaceutical directorate (Binfar & Alkes).
- While Subdit AIDS followed the instructions to collaborate with Binfar, it has become clear in recent weeks that the Binfar process will take significantly longer than required to ensure a secure national stock of ARVs.
- At current consumption, some ARVs will be out of stock in Jakarta by mid-March 2009, and others soon thereafter.
- Considering the critical situation → option of outsourcing with Unicef → short lead time period to anticipate stockout, however even though ARV is already arrived → it could not cleared out easily.
Dalam pelaksanaannya, pengadaan dan pengiriman barang sampai di Bandara berjalan lancar.

Kesulitan mulai timbul karena terjadi restrukturisasi di Bea Cukai, proses cleareance bertambah panjang dan berjalan lambat, sehingga sampai saat ini ARV masih tertahan, kecuali Aluvia yang langsung masuk ke Gudang P2ML karena dikirim langsung (PT Abbot Indonesia, produk Aluvia sudah teregister). Diharapkan 20 April 2009 sudah di gudang P2ML

Harus ada SOP khusus untuk ARV clearance
PERENCANAAN DAN REALISASI ART

- Tahun 2009 sesuai dengan perhitungan jumlah pasien 21.000 dialokasikan dana APBN Rp. 39 milyar dan GF R4 phase 2 sebesar Rp. 22 milyar → 61 Milyar rupiah/thn
- Faktor yang mempengaruhi Kesinambungan ARV
  1. Jumlah pasien bertambah → longlive treatment (inisiasi ARV baru, harapan hidup lebih lama)
  2. Perubahan regimen dalam satu lini → substitusi → kondisi pasien dan perubahan kebijakan WHO (living treatment/ medication) dan substitusi ke regimen lini kedua
  3. Kebijakan pengobatan ARV tingkat nasional → curative therapeutic (CD4 < 200) vs prevention therapeutic (CD4 < 350, estimated 50,000 and approx IDR 200 billion) dan sumber daya yang ada????
  4. Adherence/kepatuhan berobat pasien
  5. Tingkat Resistensi pada pengobatan
  6. Precise Forecasting
  7. Lead time
  8. Faktor-faktor diluar kendali Depkes (Bencana, dll)
Wacana kedepan → kesinambungan ARV

- Pendanaan multi mix: pemerintah (untuk yang tidak mampu melalui jamkesmas/askeskin), PPP (perusahaan melalui asuransi, jamsostek dll), Swadana dengan minimum subsidy (akses melalui dokter swasta yang terakreditasi dan apotik yang ditunjuk)

- Penyediaan buffer stock di tingkat provinsi/kab/kota yang mampu → one time allotment dan terkoordinasi melalui pusat (Depkes) → refresh periodically by central

- Produksi ARV generik ditingkatkan, harga dapat ditekan lebih murah

- Special treatment for ARV clearance → SOP khusus → KPA, KF, beacukai, mitra lain terkait
TERIMA KASIH