



President's Emergency Plan for AIDS Relief, Vietnam

Provision of ARV Medicines Situation Summary

July 2005

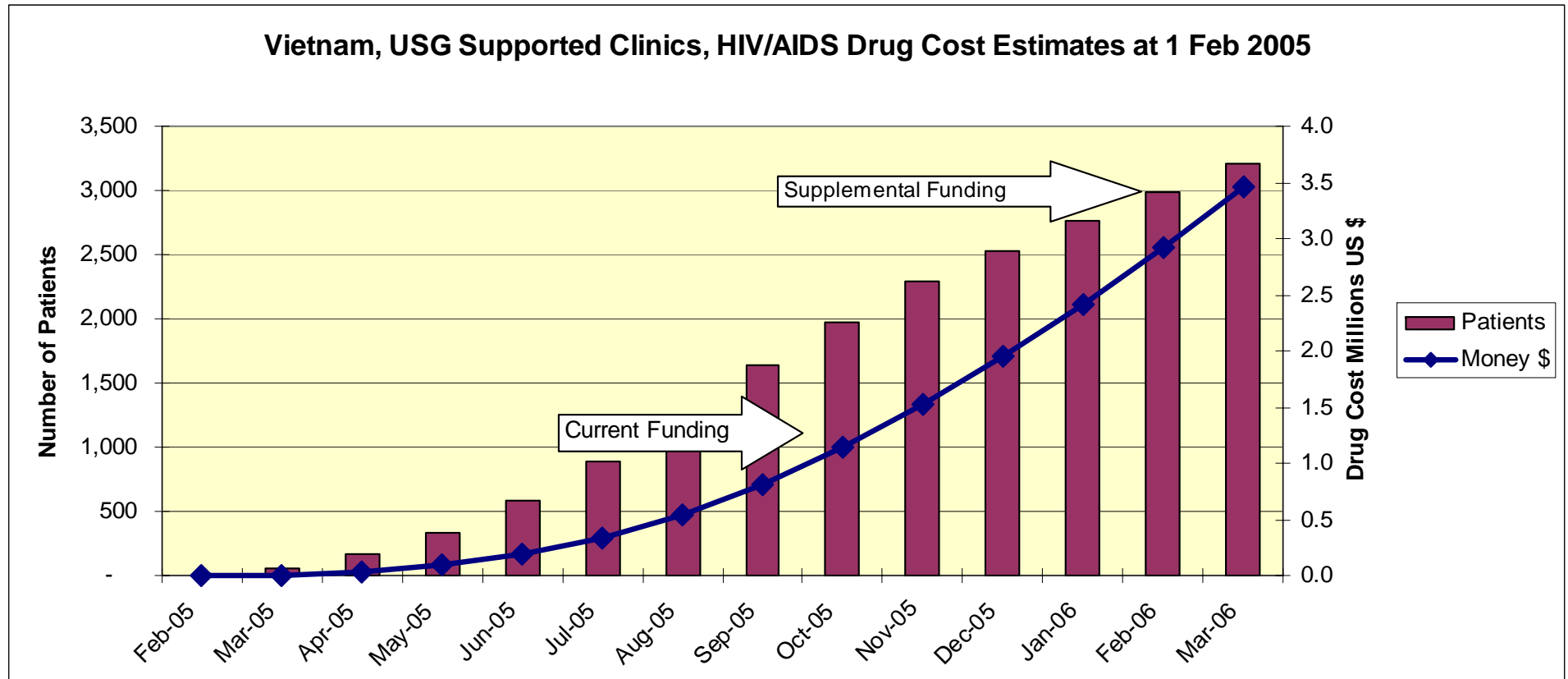


PEPFAR

- Presidents Emergency Plan For AIDS Relief
- Launched January 2003
- Vietnam 15th country to be included
- Aim – Comprehensive response through program of support to develop sustainable prevention, care and treatment programs at all levels of the health care delivery system.
- PEPFAR is in addition to activities supported by (GFATM) and other donors.



Drug Quantity and Cost Summary

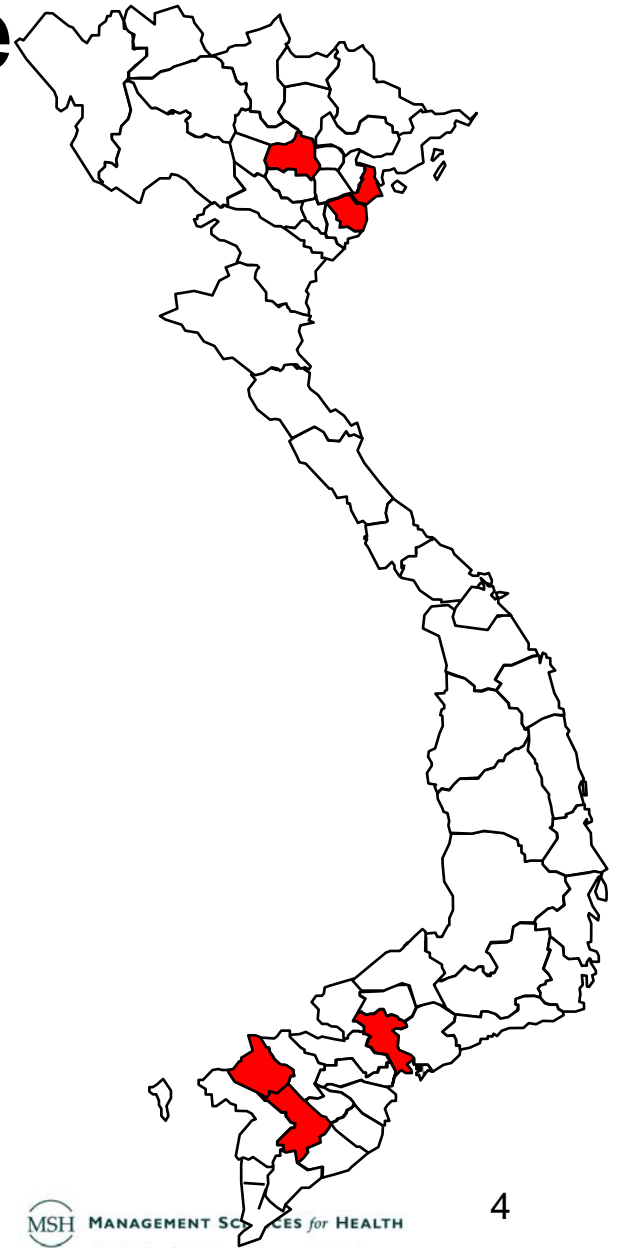


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PEPFAR Vietnam - Where

- Focus on six provinces: HCMC, Hai Phong, Hanoi, Quang Ninh, An Giang, Can Tho
- Decision made in collaboration with MOH
- These provinces contain the highest epidemiologic burden of HIV in the country and thus the highest potential impact of prevention, care, and treatment programming



Jul 05



PEPFAR AS A PERCENTAGE OF PROVINCIAL FIGURES

	HANOI	NE Coast		HCMC	MKRD		Sub total
		HAI PHONG	QUANG NINH		CAN THO	AN GIANG	
Estimated Number of PLWHA VN (2005)	17,339	21,208		50,199	61,316		150,062
Estimated Number of PLWA VN (2005)	3,468	4,242		10,040	12,263		30,012
PEPFAR TARGETS 2005/6							
PEPFAR target Number of people to receive ARV by 3/2006	605	453	401	1,509	84	84	3,136
PEPFAR Target as a percentage of PLWHA	3%	4%		3%	0.3%		2%
PEPFAR Target as a percentage of PLWA	17%	20%		15%	1%		10%
Approximate ARV cost for year 3/2005 to 3/2006	\$623,150	\$466,590	\$413,030	\$1,554,270	\$86,520	\$86,520	\$3,230,080



ARVs - Who will be doing what ?

- FHI has undertaken the procurement of the first tranche of ARVs
- MSH will be undertaking future procurements
- MSH will further be working to strengthen pharmaceutical management systems, especially in regards to integration of drug reporting into overall reporting/monitoring, supply factors and rational use of drugs



What does PEPFAR supply ?

- ALL medicines must conform to Vietnam MoH treatment protocols
- ALL medicines are approved by the MoH
- All medicines have both USA FDA and WHO 'white list' approval
- All medicines have certified certificate of analysis and quality approvals for every batch/lot



What does PEPFAR supply ?

- All standard USG procurement regulations apply to PEPFAR as to all other sources of USG funding - in essence: must meet US quality standards and regulations and observe of patent law
- In general for the first two tranches of ARVs, products from the original patent holder manufacturer have been supplied, but this may change as some generics now have USA FDA equivalence



Type	ABR	Generic Name	Trade Name	Original Manufacturer	Dosage Forms		
					Adult	PMTCT	Pediatric
Nucleoside Analog	3TC	Lamivudine	Epivir	GSK	150mg		10mg/ml
	ZDV	Zidovudine	Retrovir	GSK		300 mg 600 mg	10mg/ml
	ZDV + 3TC		Combivir	GSK	300+150mg		
	ABC	Abacavir	Ziagen	GSK	300mg		
	d4T	Stavudine	Zerit	BMS	30mg 40mg		1mg/ml
	ddI	Didanosine	Videx	BMS	25mg 100mg 200mg		
	TDF	Tenofovir	Viread	Gilead	300mg		
Non Nucleoside Reverse Transcriptase Inhibitor	EFZ	Efavirenz	Stocrin	MSD	600mg		200mg
	NVP	Nevirapine	Viramune	BI	200mg	200 mg	10mg/ml
Protease Inhibitor	NFV	Nelfinavir	Viracept	Roche	250mg		



PEPFAR Supplied Drugs Costs

- Most of the major manufacturers now supply ARVs and some OI drugs at preferential prices to LDC, LL and other special HDI classification countries
- Vietnam would NOT normally qualify for these preferential prices, but under special arrangements, 6 of the 7 major manufacturers have agreed to extend the preferential pricing scheme to Vietnam.



Drug Quantification Planning

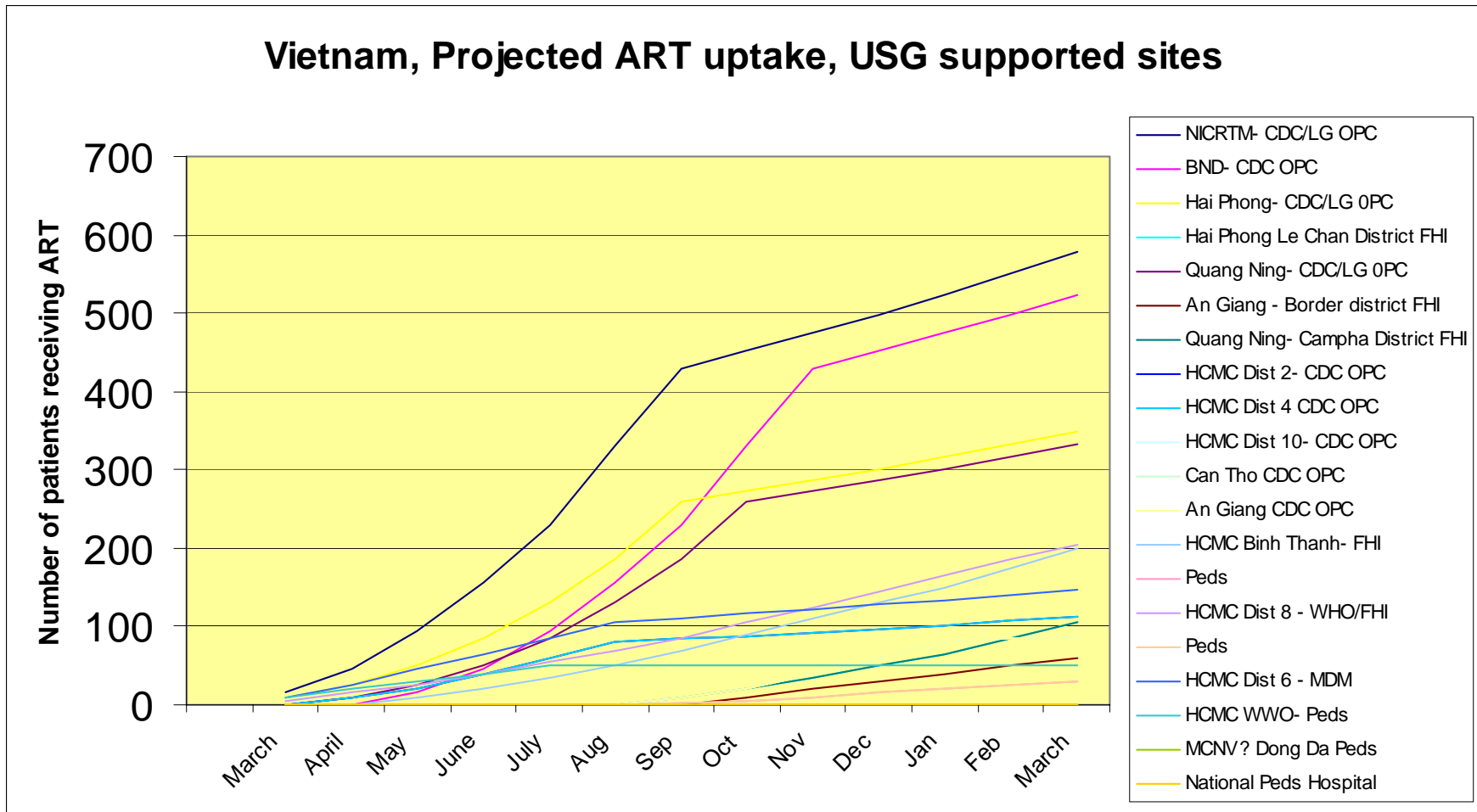
Major assumptions used in drug planning:

- MoH treatment protocols
- 70% of adult patients weigh less than 60Kg
- around 5% pediatric patients
- average weight of pediatric patients 5Kg
- around 10% second line treatment
- Newborns weight 4 Kg

Default Protocol Splits		
ADULTS		
d4T/3TC/NVP	35.00%	
d4T/3TC/EFV	35.00%	
ZDV/3TC/NVP	7.50%	
ZDV/3TC/EFV	12.50%	
DDI/ABC/NFV	10.00%	
		100.00%
PEDIATRICS		
d4T/3TC/NVP	40.00%	
d4T/3TC/EFV	40.00%	
ZDV/3TC/NVP	7.50%	
ZDV/3TC/EFV	12.50%	
		100.00%
MTCT		
ZDV/3TC/NVP	100%	
AZT	100%	



Estimated ART Uptake for USG Supported Sites



Drug Distribution Plan

- CPC No.1 to act as distributing agent
- Drugs delivered direct to individual clinic/dispensing site
- Initial delivery of estimated 3 months supply
- Thereafter clinics/sites requisition requirements up to an agreed maximum quantity for each site



DMIS Monitoring Reporting

- Initially a very basic, paper based system – 3 forms: reporting number of patients, drugs used, drug stock levels, quantities requested
- MSH RPM Plus developed ARV DMIS to be offered to treatment sites linked to ITT central system
- Standard Operating Procedures to be developed for pharmaceutical and drug management aspects

MẪU BÁO CÁO BỆNH NHÂN SỬ DỤNG THUỐC ARV (TẠM THỜI)

THỜI GIAN BÁO CÁO		Tháng		Năm	
TỔNG SỐ BỆNH NHÂN		a	b	c	d
Mức độ	Mức độ điều trị	30 ngày điều trị tiếp theo bằng thuốc	30 ngày điều trị tiếp theo bằng thuốc	30 ngày điều trị tiếp theo bằng thuốc	30 ngày điều trị tiếp theo bằng thuốc
BỘ CHỨC VỤ					
1	KT (KHOA) (KT) (KT)				
2	KT (KHOA) (KT) (KT)				
3	KT (KHOA) (KT) (KT)				
4	KT (KHOA) (KT) (KT)				
5	KT (KHOA) (KT) (KT)				
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8	KT (KHOA) (KT) (KT)				
9	KT (KHOA) (KT) (KT)				
10	KT (KHOA) (KT) (KT)				



Dispensing Drug Regimen
d4T (40mg) + 3TC + NVP
 patients OVER 60 Kg using 40 mg d4T

d4T	3TC	NVP
 40mg tablet 40mg tablet	 150mg tablet 150mg tablet	 250mg tablet 250mg tablet
Total per day: _____ Total per day: _____	Total per day: _____ Total per day: _____	Total per day: _____ Total per day: _____



Challenges

- Vietnam is in 'competition' with the other 14 PEPFAR countries to obtain preferred pricing ARVs supply from the manufacturers at a time of limited immediate availability
- Normally 4 to 6 months lead-time for drugs
- Unclear import, registration & distribution guidelines and systems for such new drugs
- Requirement for dynamic drugs management



Current Status

- ARVs for approx 3,600 patient months of treatment now in stock at CPC # 1 Hanoi
- 3 months supply issued to first phase treatment centers
- Further 6,300 patient months of treatment on order



Summary

- First line, second line, pediatric and PMTCT, ARVs are in country
- First phase physical drug distribution to treatment sites has been made
- MSH will be providing further procurement and pharmacy technical assistance services

