



Ministério da Saúde



FIOCRUZ

FUNDAÇÃO OSWALDO CRUZ



Ministério da Saúde
Fundação Oswaldo Cruz
Escola Nacional de Saúde Pública Sergio Arouca

Experiencias con indicadores de Políticas Farmacéuticas

Vera Lucia Luiza MSc, ScD

Nucleos for Pharmaceutical Policies – PAHO-WHO CCPP

Feb, 2009

Carlos Monte ©

Pharmaceutical services to PLWHA and patient satisfaction

Coordinated by
Vera Lucia Luiza and Angela Esher

Evaluative question

Is Dispensation being performed in an adequate and quality way in order to promote rational use of medicines and satisfy users needs?

Methodology

- ▶ **Survey**
- ▶ **Rapid assessment method (RAM)**
- ▶ **Sample: Ten States (convenience sample, including the highest prevalence state in each region), 18 municipalities and 29 dispensing facilities (randomly selected, probability proportional to the total of PLWHA subscribed), 1425 users interviews**
- ▶ **Triangulation of methods**
 - ▶ **Public dispensing facilities – direct field observation, interview, document consultation**
 - ▶ **User (over 18 y.o.), Dispensers, Pharmacists and Prescribers – face-to-face interview**
 - ▶ **Managers at Municipality and State Level – telephone interview**

Framework

Pharmaceutical services indicators (structure and process)	Dimensions	Subdimensiones	Components	User Satisfaction (Outcome indicators)
	Timing	Convenience	Geographical accessibility Service organization Waiting time Potential for free choice of services and health professionals	
	Availability	Presence of medicine	Availability of specific medicines in need Availability of amount of medicines in need	
	Adequacy	Technical quality of dispensation Quality of medicines Accommodation Interpersonal relation	Accuracy Quality Effectiveness Aspect Cleanliness Comfort Signaling Autonomy Dignity Confidentiality	

PS Indicators

Adequacy

Adequacy (accommodation)

- 1 Average score of accommodation in the dispensation area

Adequacy (technical aspects of dispensation)

- 2 DF with supervision of a pharmacist
- 3 % users receiving information about medicines
- 4 % users that know how to take their medicines
- 5 % prescrições completas
- 6 % medicamentos adequadamente rotulados
- 7 A unidade dispensadora dispõe de fonte válida de informação sobre medicamentos
- 8 A unidade dispensadora dispõe de material educativo para fornecimento aos usuários
- 9 % farmacêutico e dispensadores receberam treinamento sobre aids ou medicamentos (ARV ou MIO)
- 10 A unidade dispensadora dispõe de procedimento escrito para a atividade de dispensação
- 11 A unidade dispensadora dispõe da lista pactuada de MIO
- 12 A unidade dispensadora dispõe das Recomendações para Terapia ARV

Adequação (qualidade dos medicamentos)

- 13 % de itens de BPE (Boas práticas de estocagem) atendidos no local de estocagem dos medicamentos
- 14 % de itens de BPE (Boas práticas de estocagem) atendidos no local de dispensação dos medicamentos
- 15 % de medicamentos com validade vencida no estoque de medicamentos ou na área de dispensação

Adequação (aspectos interpessoais)

- 16 A unidade dispensadora proporciona privacidade no atendimento
- 17 A unidade dispensadora dispõe de espaço para que os usuários discutam as decisões sobre seu tratamento

Availability

- 18 % medicines available
- 19 Stockout duration
- 20 A unidade dispensadora dispõe de SICLOM em funcionamento
- 21 A unidade dispensadora realiza controle de estoque

Oportunidade (conveniência)

- 22 Tempo médio de trajeto da residência até a unidade dispensadora
- 23 Tempo médio de espera na fila da unidade dispensadora

Users profile

- 1412 users interviewed
- 62% male
- 54.8% single
- 44.9% white (self declared)
- 38.9% paid work, 28.2% retired or pensioner
- 71.3% economic class C and D
- 25.8% 4 to 8 years of study e 29.3% studied at least 11 years;
- 39.4 average age;
- 5.8 years of know serum positive status;
- 4.7 years under ARV treatment;
- Most of users self evaluated their health status as good (53.7%) or very good (41.4%) and 4.9% as bad or very bad (possible bias)

Results According to Dimension

Timing / Convenience

Oportunidade/ Conveniência

Time to arrive DF	68,4 min
Waiting time at the DF counter	10,9 min

Time to arrive the DF and satisfaction with travel time

Satisfaction with time to arrive DF	#	%	Average travel time (minutes)	CI	
Satisfied	409	29	30,2	27,1	33,4
Partially satisfied	139	10	36,9	31,7	42,1
Partially unsatisfied	239	17	56,4	48,6	64,2
Unsatisfied	615	44	105,7	97,3	114,0
Total	1402	100	68,5	64,0	72,9

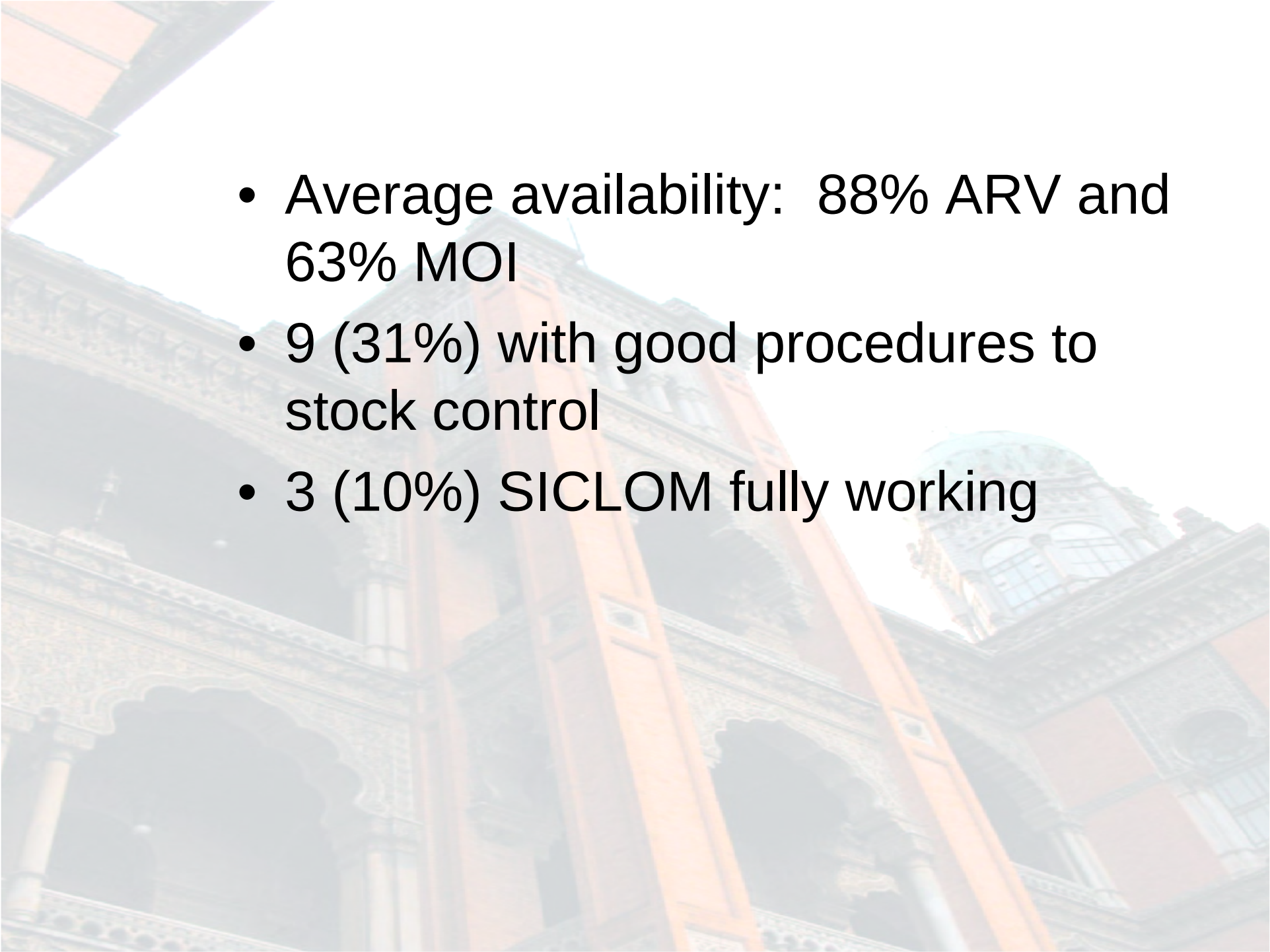
Waiting time and user perception

Satisfaction with waiting time at the DF counter			Average waiting time		
	n	%		CI	
Satisfied	846	60	6,0	5,2	6,7
Partially satisfied	215	15	8,6	6,9	10,3
Partially unsatisfied	219	16	16,9	13,0	20,7
Unsatisfied	129	9	36,9	27,8	46,0
Total	1409	100	10,9	9,7	12,1

Availability of medicines

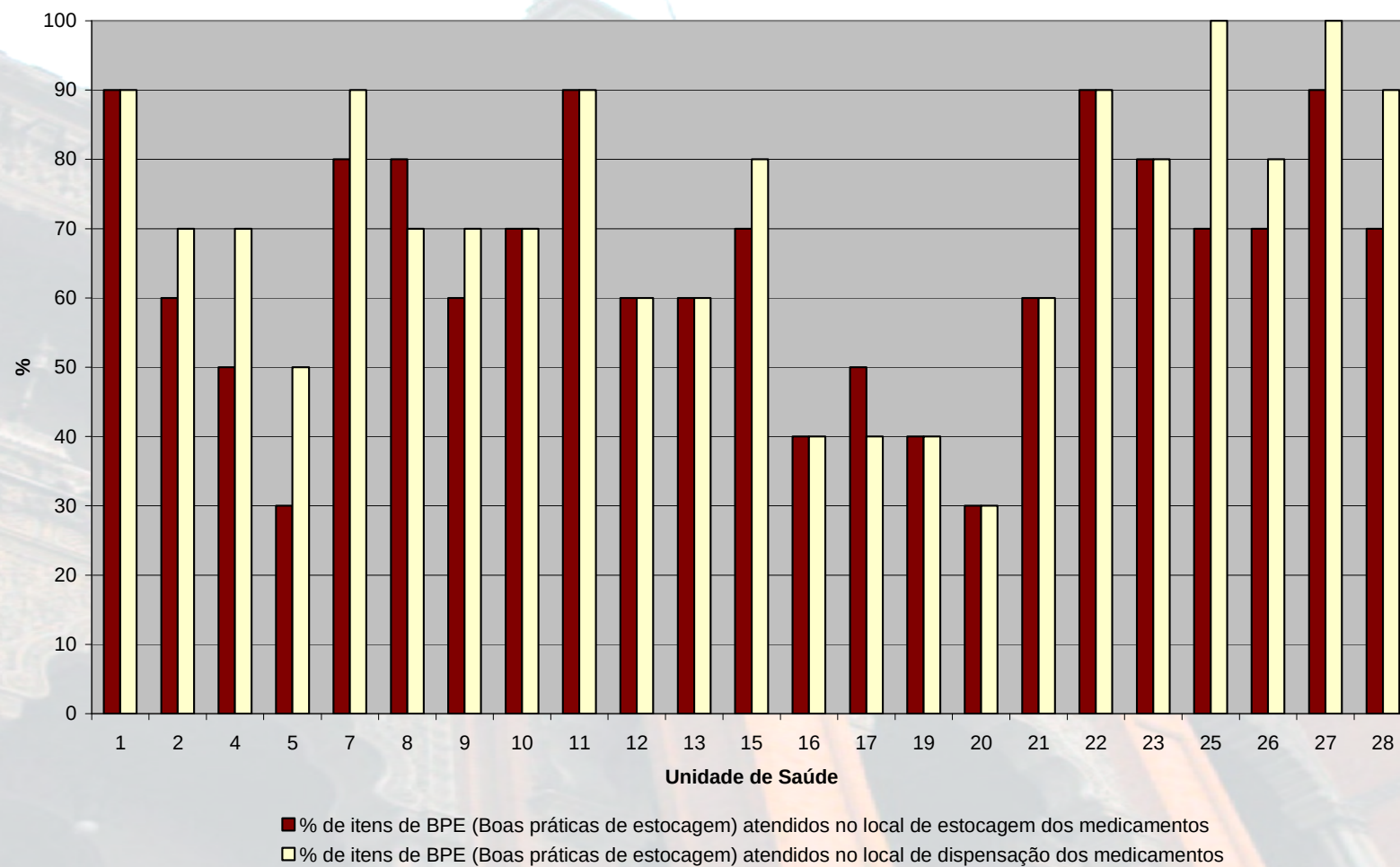
DF with products available, 2005.

Medicamento	%
Medicines for opportunistic infection and other products	
Condoms	41%
Itraconazole Cápsulas 100 mg	52%
Sulfametoxazole + trimetoprima comp 400+80	59%
Ciprofloxacino comp 500 ou 250 mg	69%
Aciclovir 400mg ou valaciclovir 500mg comp	72%
Fluconazol comp 100 mg	86%
ARV	
Abacavir ABC Comprimido 300mg	66%
Amprenavir APV Cápsula 150 mg	72%
Atazanavir ATV Cápsulas de 200mg	83%
Saquinavir SQV caps 200mg	83%
Ritonavir RTV caps 100 mg	86%
Didanosina ddl comp tamponados 100mg / lib. entérica de 400 mg	90%
Lopinavir/ Ritonavir LP/r caps 133,33/33,3mg	90%
Tenofovir TDF Comprimido 300mg	93%
Efavirenz EFV Cápsulas de 600mg	93%
Lamivudina 3TC 150mg + Zidovudina AZT 300mg	93%
Estavudina d4T Cápsula 40mg	97%
Indinavir IDV Cápsula 400mg	97%
Nelfinavir NFV comp 250mg	97%
Nevirapina NVP Comprimido 200mg	97%

- 
- Average availability: 88% ARV and 63% MOI
 - 9 (31%) with good procedures to stock control
 - 3 (10%) SICLOM fully working

Adequation

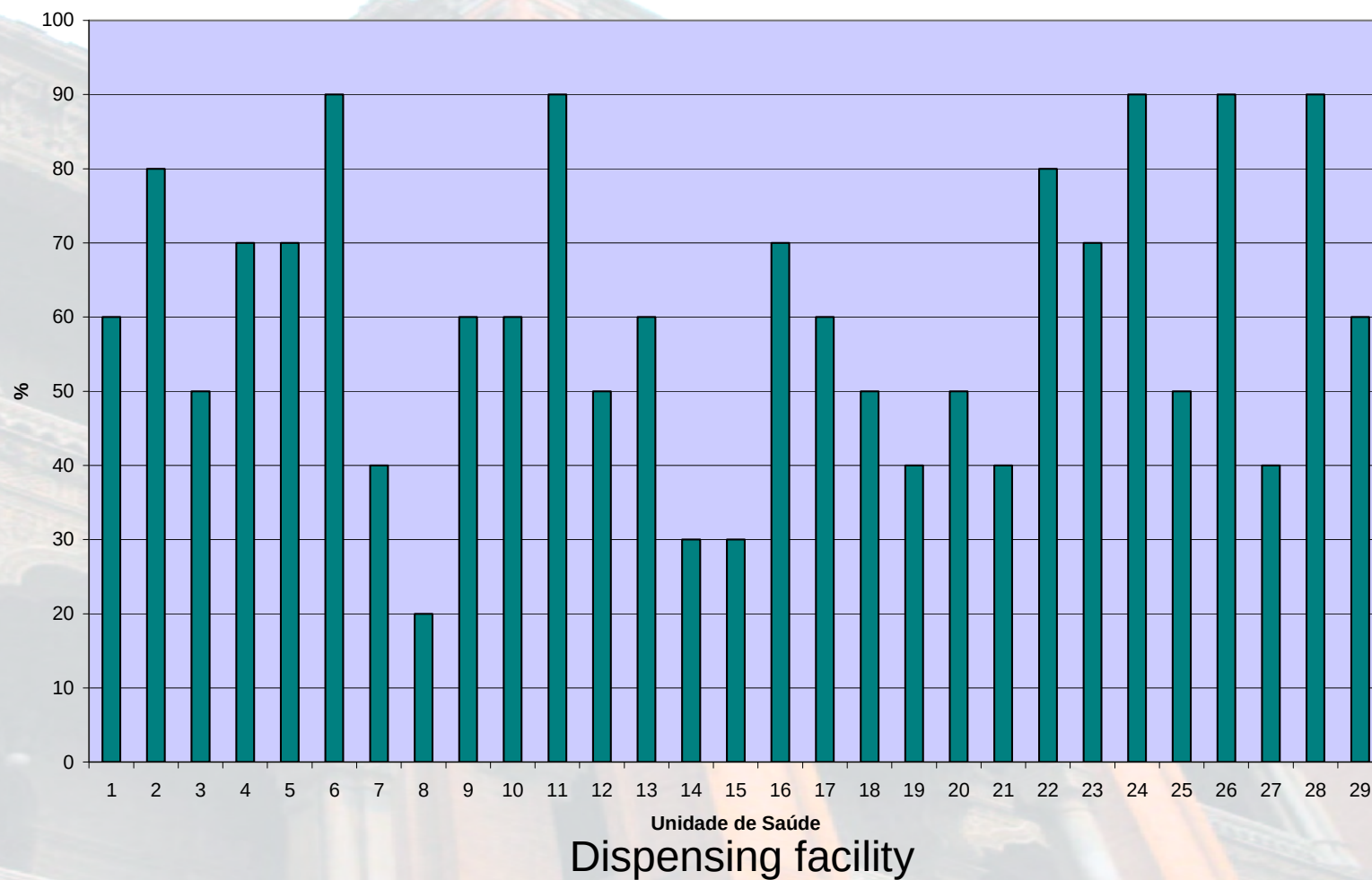
Good storage practice



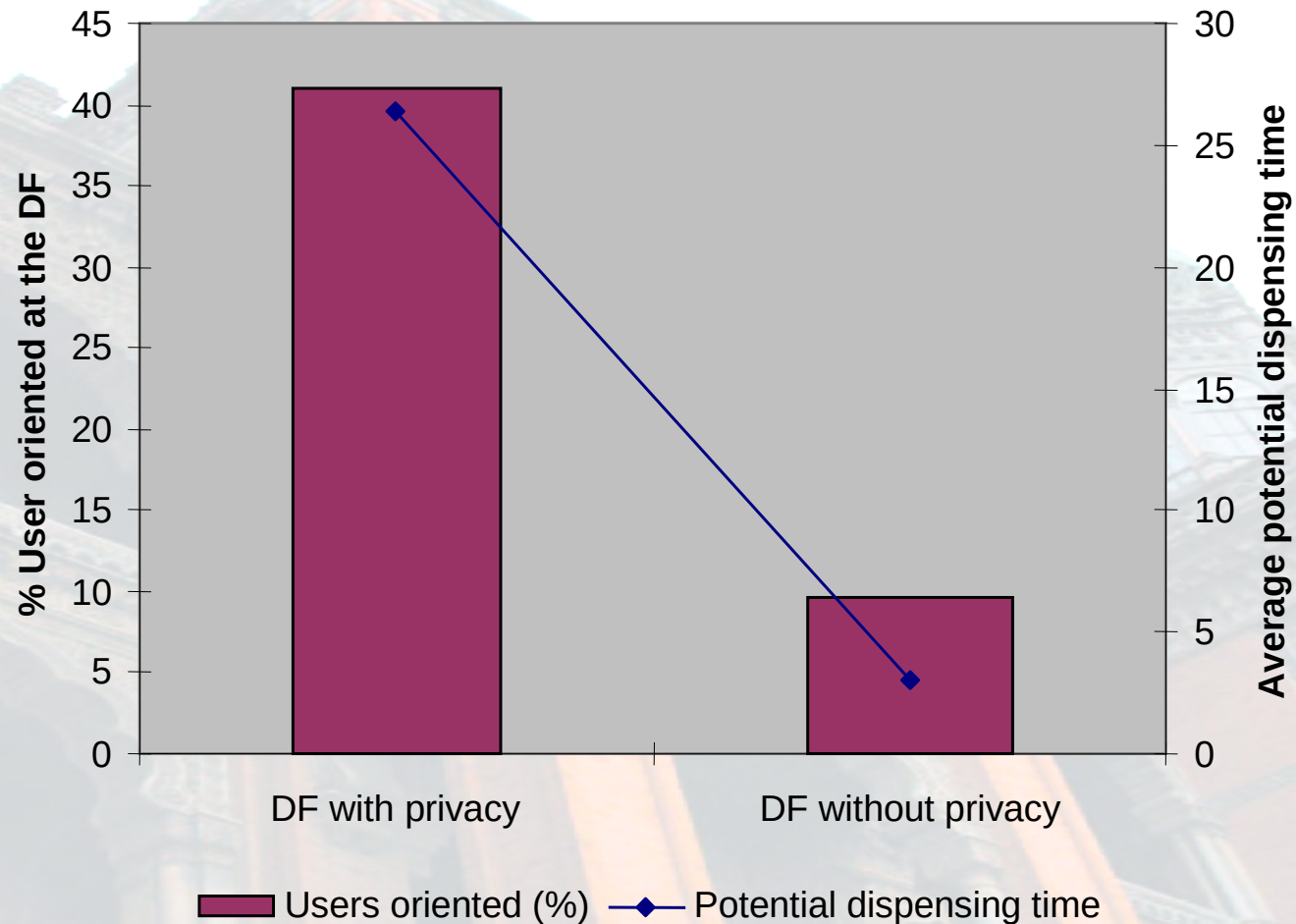
Prompt access to de AIDS Treatment Guideline in the health facility

Kind of Treatment Guideline	Physician	Pharmacy
Adult	66,7%	75,9%
Children	37,5%	64,0%
Pregnancy	53,6%	57,7%

Rank on accommodation condition in the dispensing area



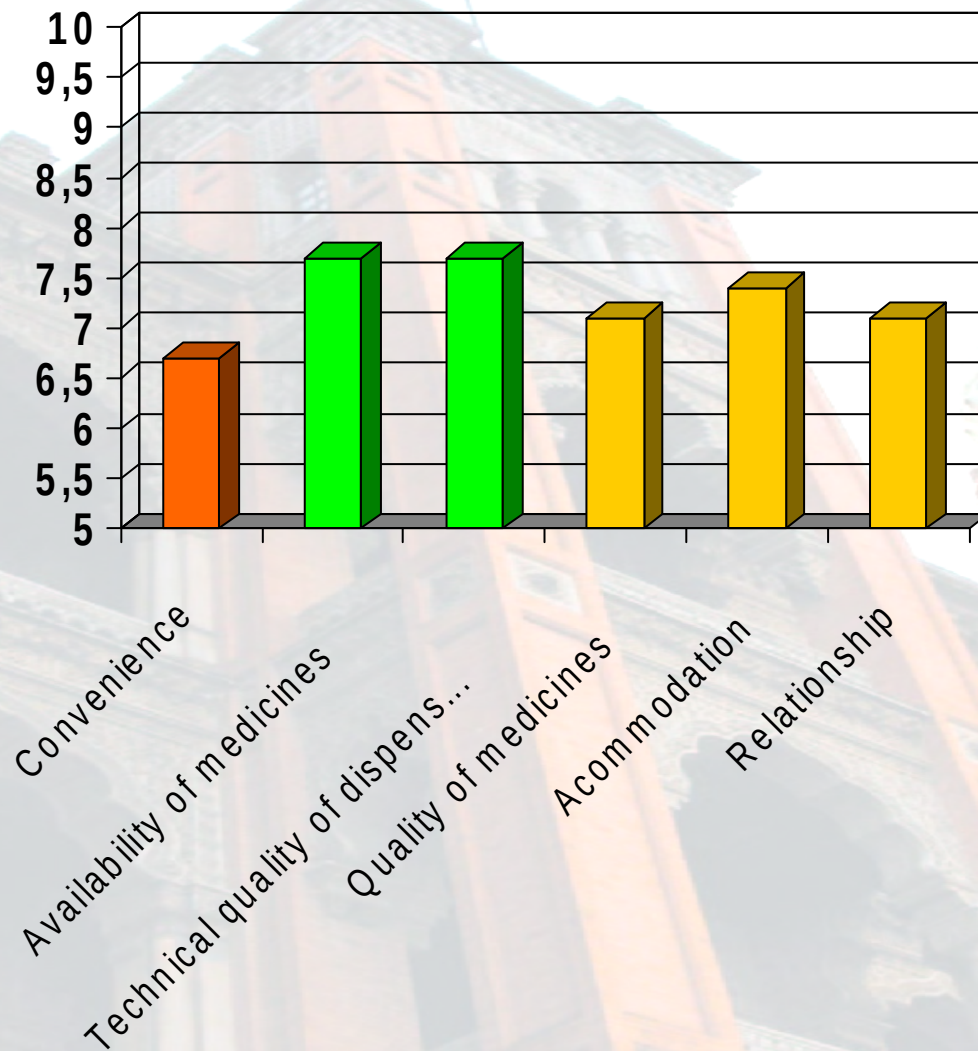
Patients oriented during dispensation and privacy conditions of the dispensing area





Users Satisfaction

Users satisfaction score, Brazil, 2005



User satisfaction

- Aspects declared as most important: availability of medicines and interpersonal relationship
- Aspects found to influence most satisfaction level: accommodation and interpersonal relationship

Mains positive aspects

- High availability of ARV
- All States and Municipalities have the Opportunistic Infection and STD Medicine List updated
- 31% DF had Standard Operational Procedures to dispensation of medicines
- No expired medicines were found – the problem exist, but it residual
- Most users knew how to use their medicines
- DF with better accomodation, specially privace conditions are able to orient patients concerning to rational use

Main problems

- There were found some Medicines list with bad or incomplete specified medicines
- There are Municipalities with inadequate coverage of treatment offer
- There were found problems on the availability of MOI
- Problems with the stock control
- Pharmacists are not totally contributing to patient care
- 66% DF did not offer privacy conditions to dispensation of medicines to PLWHA

Following steps

- Results of this study were disseminated in papers, technical and management meetings, including civil society
- Papers and book chapters submitted or under preparation
- Thesis and dissertations
- A Working Group with was created by the National Aids Program to face problems showed by the study



Monitoreo de la negociación de precios de ARV en América Latina y Caribe

Maruja Crisante Nuñez

Claudia Garcia Serpa Osorio-de-Castro

Maria Auxiliadora Oliveira



Antecedentes

- Evaluación de la Primera Ronda (Lima, 2003) como subsidio para la segunda (Buenos Aires, 2005)
- Trabajo desarrollado en Junio 2005
- Visita a Paraguay, Uruguay y Argentina, y entrevistas con actores-clave de los países
- Fue construido un primer marco conceptual

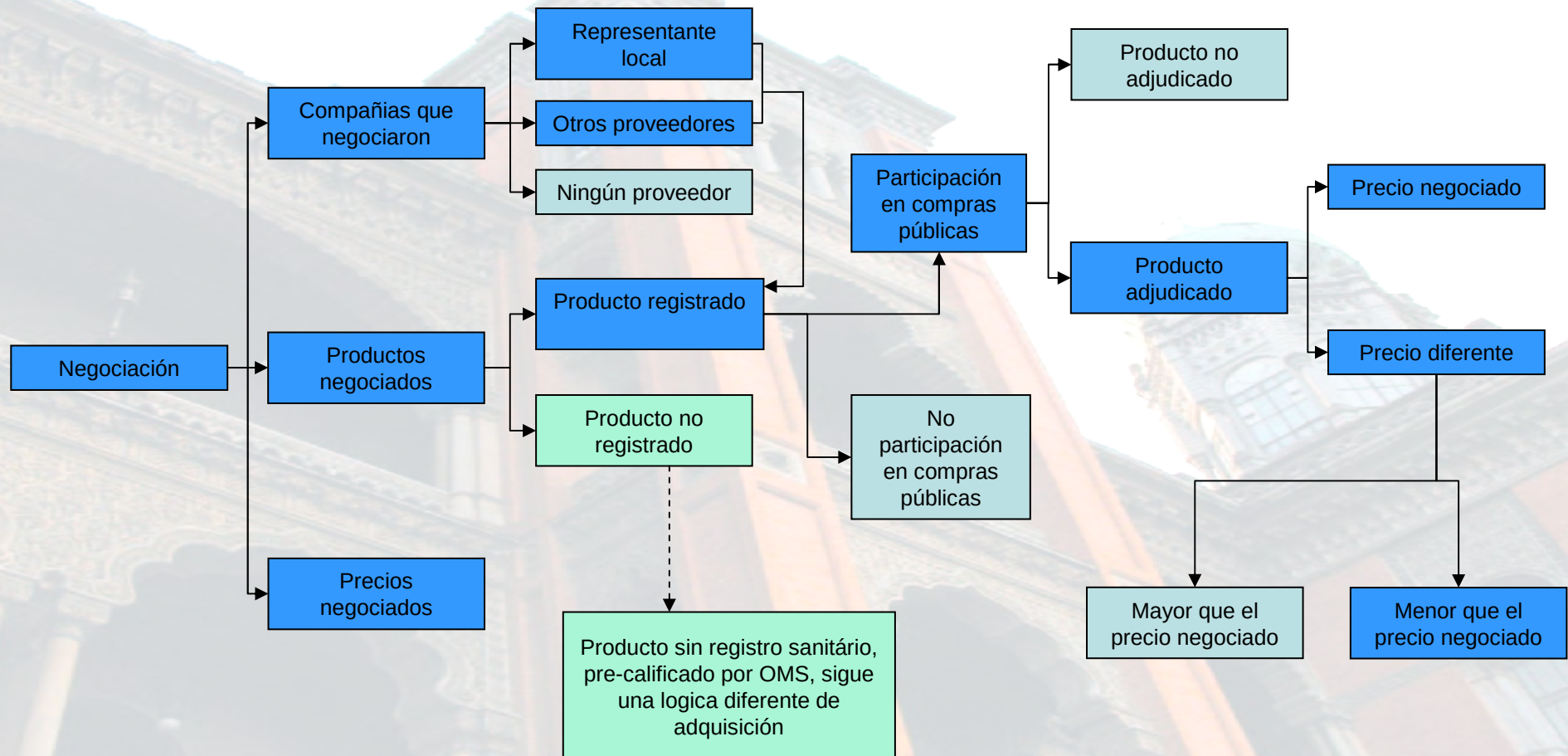
Propuesta

En el seminario "Alternativas para el Financiamiento de los ARVs en América Latina, Angola y Mozambique", Río de Janeiro, Brasil, (Septiembre, 2005), los países participantes de la Región plantearon la necesidad de desarrollar y testar una metodología para el monitoreo de la implantación de las negociaciones de precios de ARV en LAC

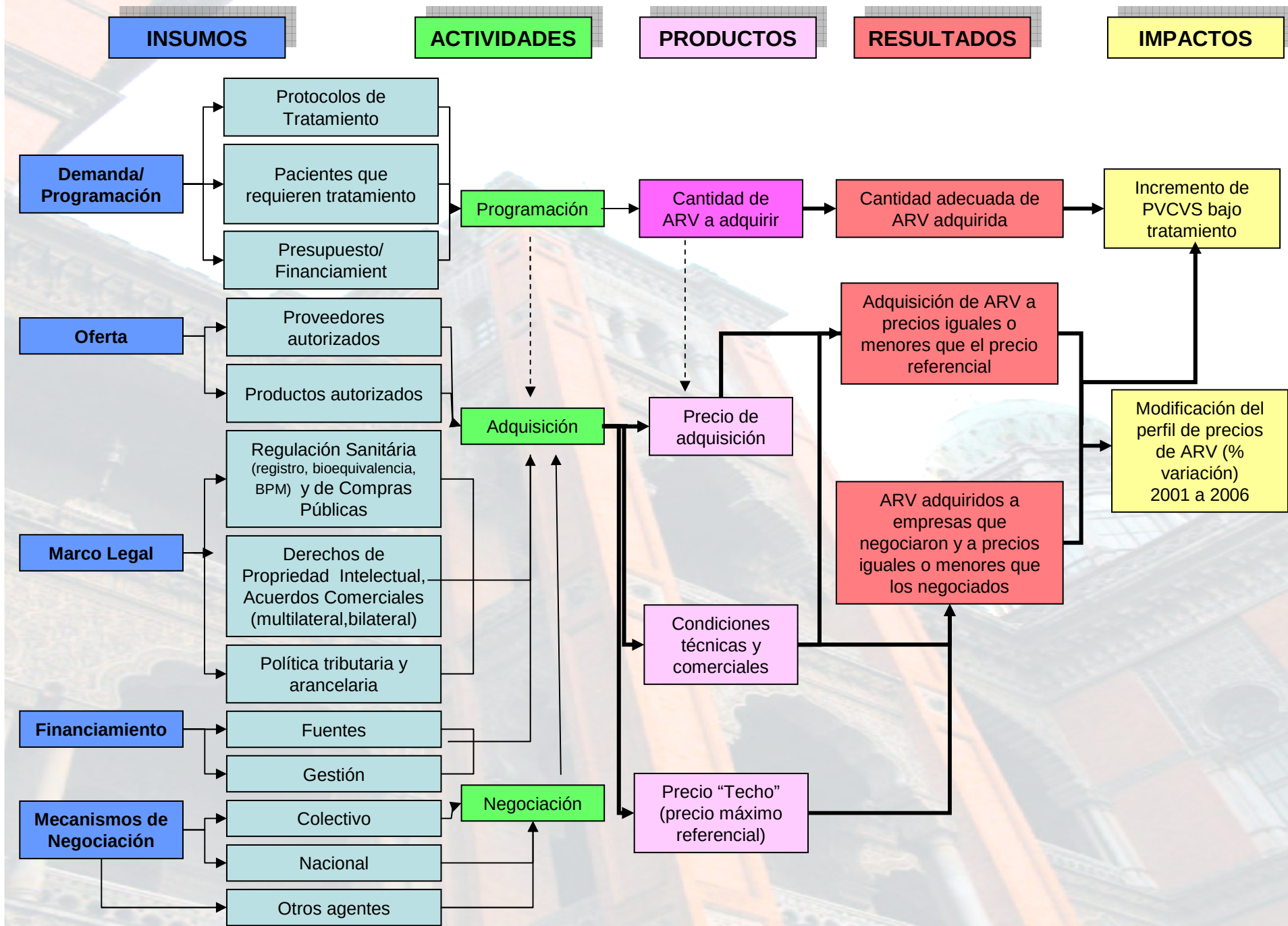
Objetivos

- Monitorear la implementación de las negociaciones en los países
- Enfatizar los procesos de negociaciones de precios de ARV y los requisitos para que los países tengan éxito en los procesos de negociación

Proceso de implementación de la negociación de precios de ARV en compras públicas



Modelo Teórico de la Implementación de la Negociación de Precios en Países de América Latina



Planilla de indicadores

Indicator	Details	Source	Evaluation criteria		
			Feasibility	Pertinence	Sensitivity
Component: Demand					
Existence of a national system of updated epidemiological information on HIV/AIDS cases	System that registers, revises and publishes at least every 6 months information on the morbidity and mortality for all age groups as well as the number of cases (including, for example, the number of notified cases that require and are receiving ARV treatment)	National Program of HIV/AIDS Department of Epidemiology	High	Yes	Medium
Existence of a treatment guidelines for HIV/AIDS enforced in the country	Existence of a treatment guidelines approved by the Ministry of Health and in force in the country	National Program of HIV/AIDS	High	Yes	High
Budget annually allocated for purchasing ARV	Amount allocated in the official budget for the sectors that purchase ARV medications	National Program of HIV/AIDS	Medium	Yes	Medium
Budget annually allocated for purchasing ARV	Budget/ number of patients per line of treatment	National Program of HIV/AIDS	Low	Yes	Medium
Component: Supply					
Nº of manufacturers of ARVs in the country	Total number of manufacturers of ARVs in the country	Drug Regulatory Agency (DRA)	High	Yes	Medium
Nº of pharmaceutical companies authorized to manufacture, import and market ARV medicines included in the EML or treatment protocol	Number of companies that have permission of the health authority to manufacture, import or market ARV medicines included in the EML or treatment protocols in the country	DRA	Medium	Yes	Medium
% of ARVs registered in the country produced by manufacturers involved in price negotiations	Percentage of ARV medicines that have market approval by the country health authority and are produced by manufacturers involved in price negotiations	DRA	Medium	Yes	Medium
% of ARVs in the national EML or in the treatment protocol under patent protection	Percentage of ARV medicines included in the Essential Medicines List or in the official treatment guideline that are under patent protection	DRA / Patent Office	Low	Yes	Low
% of ARVs in the EML or in treatment protocols approved by country health authority	Percentage of ARV medicines that are included in the Essential Medicines List or in treatment protocols that have market approval by health authority	DRA	Medium	Yes	Medium
% of ARVs in the EML or treatment protocol with only one provider in the country	Percentage of ARV medicines that are included in the Essential Medicines List or in treatment protocols for which there is only one provider in the country	DRA	Medium	Yes	High

valoración

Validación

La validación fue realizada en dos fases:

- 1) Por consenso de especialistas
- 2) Estudio piloto en 3 países: Perú, Honduras y Barbados

Puntos importantes a establecer

Antes de iniciar la aplicación de la metodología, el equipo responsable por la planificación del estudio y por la recolección de datos deberá, no solamente pensar en los detalles logísticos, sino también ...

Respecto a los precios

Estratificación

- Precio Unitario Final (que incluya impuestos y aranceles)
- Precios Unitario (FOB o CIF o DDU) sobre el cual la Entidad compradora deberá efectuar pagos adicionales de desaduanaje, aranceles, etc.

Indexación (usualmente a dólar americano)

Cálculos en caso de más de una compra por año

- La mediana de los precios
- Promedio ponderado total - en el caso de contar con la información de las cantidades adquiridas en cada proceso de compra en cada año
- Asumir como precio de análisis el obtenido en la compra o compras que representen el 80% del valor financiero total en el año para ARV
- Costo anual/paciente para el medicamento ARV X, el que se determina sobre la base de cantidad de pacientes tratados con un medicamento ARV dado en un año y el costo total anual para este medicamento. Este criterio se justifica o cuando no importa el número de compras por año o cuando existe menos de 1 compra por año

Respecto a la aplicación de la metodología

- La viabilidad de la interiorización de la propuesta a nivel de los países que participaron en procesos de negociaciones de precios de ARV
- El monitoreo de precios nos es suficiente para el monitoreo de los resultados de las negociaciones. Por lo tanto, se efectuará una descripción de los componentes establecidos en el modelo lógico para cada país, relacionado la cadena de insumos, actividades y productos a los resultados
- Una metodología para ser utilizada directamente por los países de forma regular y periódica

Planificar es preciso

- Iniciativa del gobierno federal de brasil, coordinada by Fabiola Vieira
- Propuesta de realizar 61 seminarios con 100 municipalidades cada en un periodo de 3 meses
- Presentación de la propuesta, discusión de los problemas de los servicios farmacéuticos, imagen-objetivo

Niveles de gobierno	Periodo de planificación	Formalização do planejamento
Municipalidades	2007 a 2008 (2 aos)	• Plan operativo
	2009 a 2012 (4 anos)	• Plan estratégico
Estados	2007 a 2010 (4 anos)	• Plan estratégico

Propuesta de planificación em 3 pasos

1. Preparación y organización de los talleres
2. Autoevaluación – situación actual, meta, prioridad
3. Hoja de ruta

Planificar es preciso

1. Gestão da Assistência Farmacêutica – Capacidade para realizar a gestão do Ciclo da Assistência Farmacêutica							
Capacidade para	Estágio Atual	Estágios de desenvolvimento da capacidade			Estágio Meta	Indicador	Prioridade (1 a 3)
		1º	2º	3º			
Estruturar e organizar os serviços de Assistência Farmacêutica.		Não há recursos financeiros, infra-estrutura e de pessoal adequados para os serviços de Assistência Farmacêutica.	Alguns serviços de Assistência Farmacêutica estão estruturados e organizados.	A maioria dos serviços de Assistência Farmacêutica está estruturada e organizada.		Indicador 3 = Porcentagem de serviços de Assistência Farmacêutica em condições adequadas de funcionamento.	
Avaliar as ações de Assistência Farmacêutica		Não existe um sistema de monitoramento e avaliação das ações de Assistência Farmacêutica ^[4] .	Coleta esporádica de dados para monitoramento e avaliação, não havendo uma estratégia clara para interpretação.	Coleta rotineira de dados de monitoramento e avaliação em todas as atividades, os quais são utilizados para melhorar as ações de Assistência Farmacêutica.		Indicador 4 = Existência de procedimentos para o monitoramento da Assistência Farmacêutica por meio de indicadores.	

Capítulo Assistência Farmacêutica do Plano de Saúde

<u>Dimensão</u>							
Capacidade para	Meta	Ações	Período de execução	Responsável	Indicador	Prioridade	Órgão/Instituto

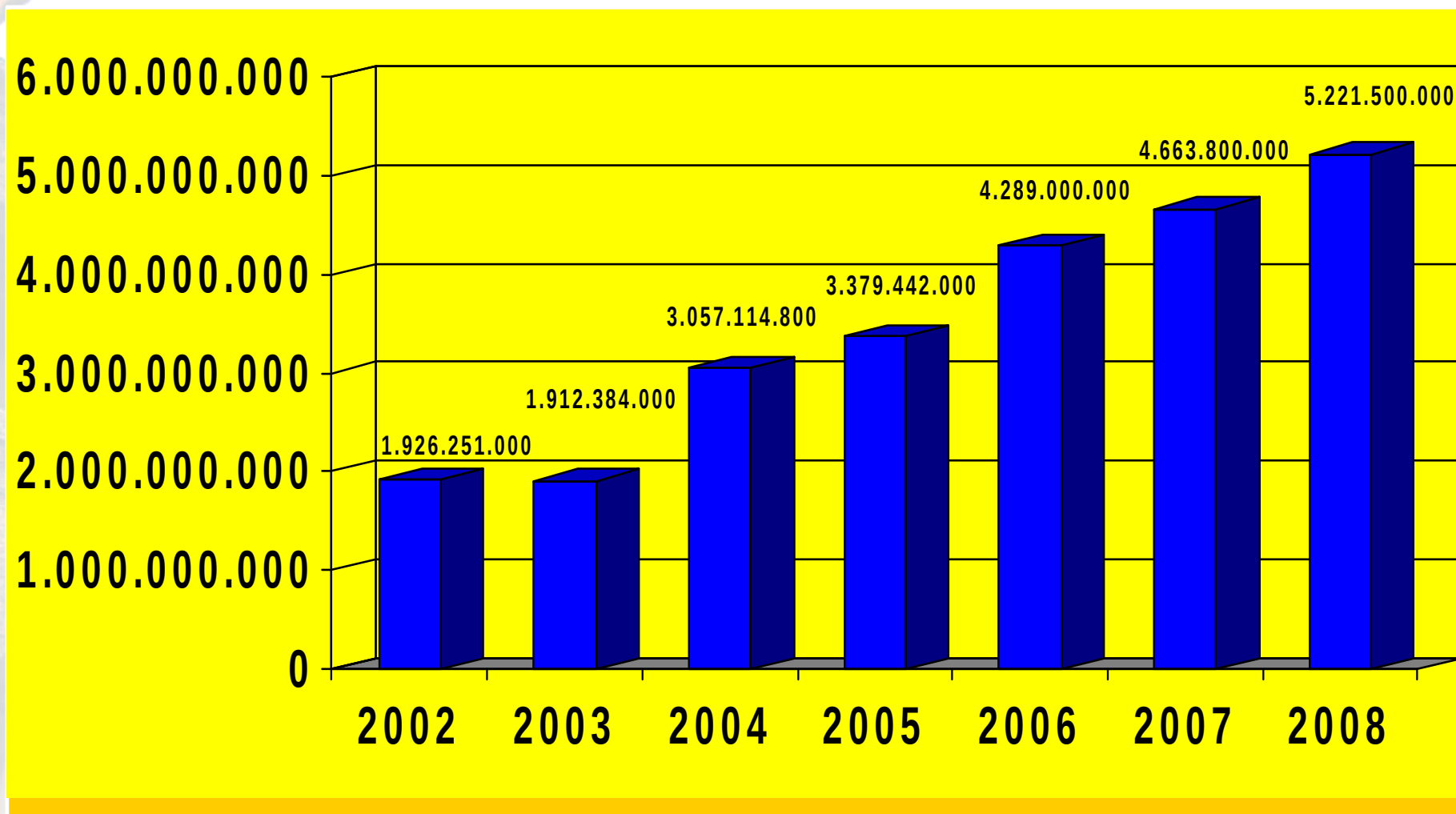
São transportados da planilha de auto-avaliação da capacidade

Propuestas en curso en Brasil

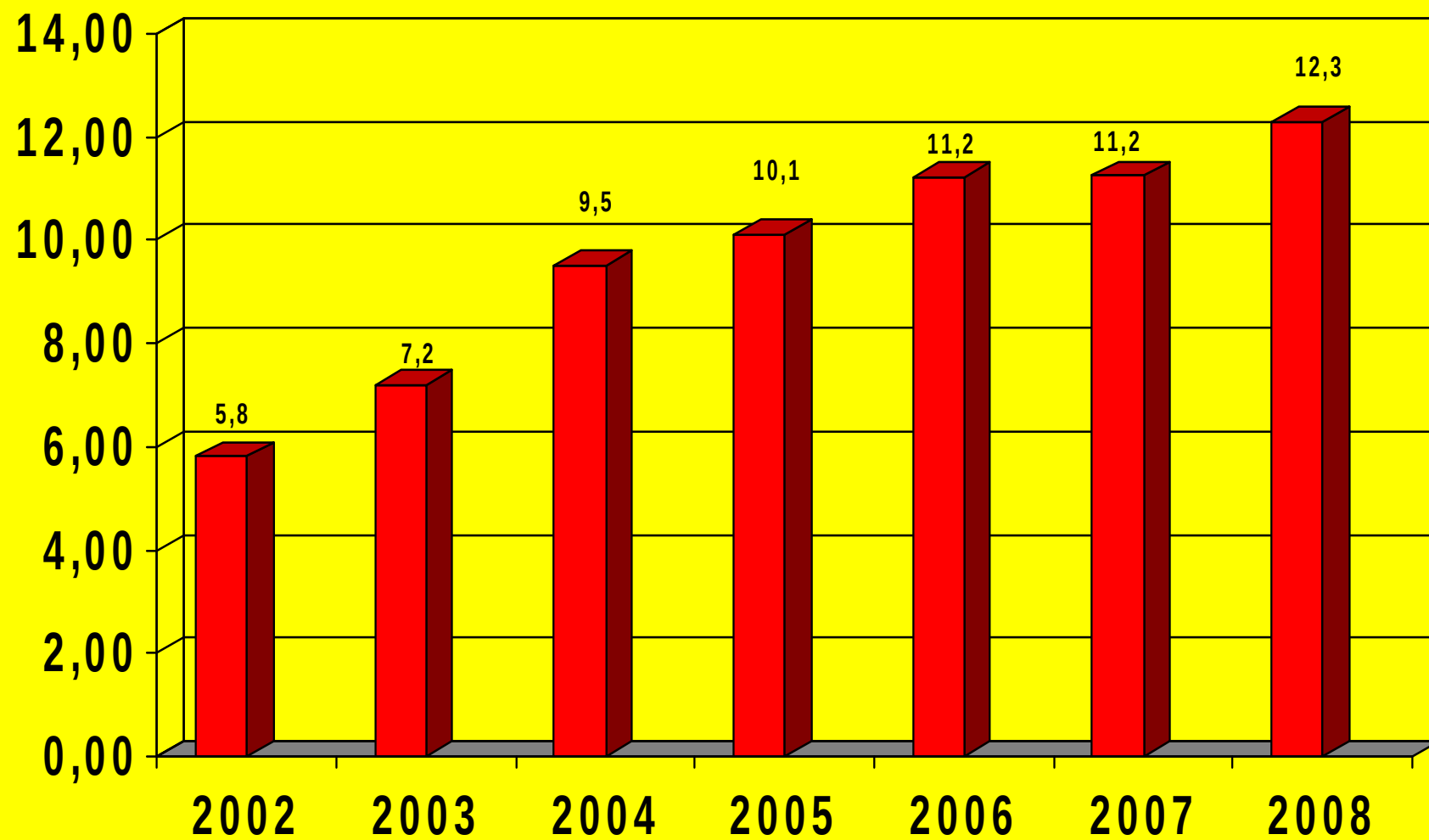
Estrategias en curso en cuando a la organización de los SF en Brasil

- Enseñanza
- URM
- Regulación (genéricos, propaganda, precios)
- Financiación pública
- Farmacia popular
- Remedio en la casa
- Inversión el investigación
- Inversión en la infraestructura de lo servicios

Evolution of main expenditures on medicines by the MoH



Expenditures on medicines as % of total federal expenditures on health



Realized Access to Medicines

- HH survey 2004 (WHO methodology-acute diseases):
all - 89.6%, some - 8.5%, none - 8.5% → 62.4% in
private pharmacies, 22.8% public dispensaries
- WHS 2005: all - 87%, most - 5%, few or none - 8%

*From people that not accessed all or most medicines 55% - WHS
and 62.8% HHS declared not to be able to afford them*

Encuesta de Presupuesto de los Hogares - 2003

Gasto promedio mensual de hogar con asistencia en salud

Grupo de gasto = Remedio

Total = R\$ 46.44

Forma de obtención del producto o servicio

Brasil	Monetaria – gasto de bolsillo	38.60
	No monetaria – financiamiento público	5.79
	No monetaria – donación (empresas, familias)	1.70
	No monetaria – otras (p.ej. muestras gratis)	0.35

Propuestas en curso

- INS – Encuesta Nacional de salud
- PNAUM – investigación Nacional de Acceso y Uso de Medicamentos
 - Seminario para difusión de experiencias y desafíos metodológicos

Aspectos generales para la discusión

- Procesos de formulación – implantación – evaluación de política tienen que estar vinculados
- Metodologías baratas, factibles x confiables
- Fortalezas y limitaciones conocidas y discutidas
- Respuestas a las necesidades de los países