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# The selection of essential medicines for reproductive health

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# Essential medicines

- **The concept of essential medicines**

**A limited range of carefully selected essential medicines leads to better health care, better drug management, and lower costs**

- **Definition of essential medicines**

**Essential medicines are those that satisfy the priority health care needs of the population**

**(Report to WHO Executive Board, January 2002)**



## History of the WHO Model List of Essential Drugs

- 1977 First Model list published, ± 200 active substances
- List is revised every two years by WHO Expert Committee
- 2002 Revised procedures approved by WHO
- Last revision (March 2005) contains 306 active substances

*The first list was a major breakthrough in the history of medicine, pharmacy and public health*

Médecins sans Frontières, 2000



# Full description of essential drugs (Expert Committee Report, April 2002)

**Definition:** Essential medicines are those that satisfy the priority health care needs of the population

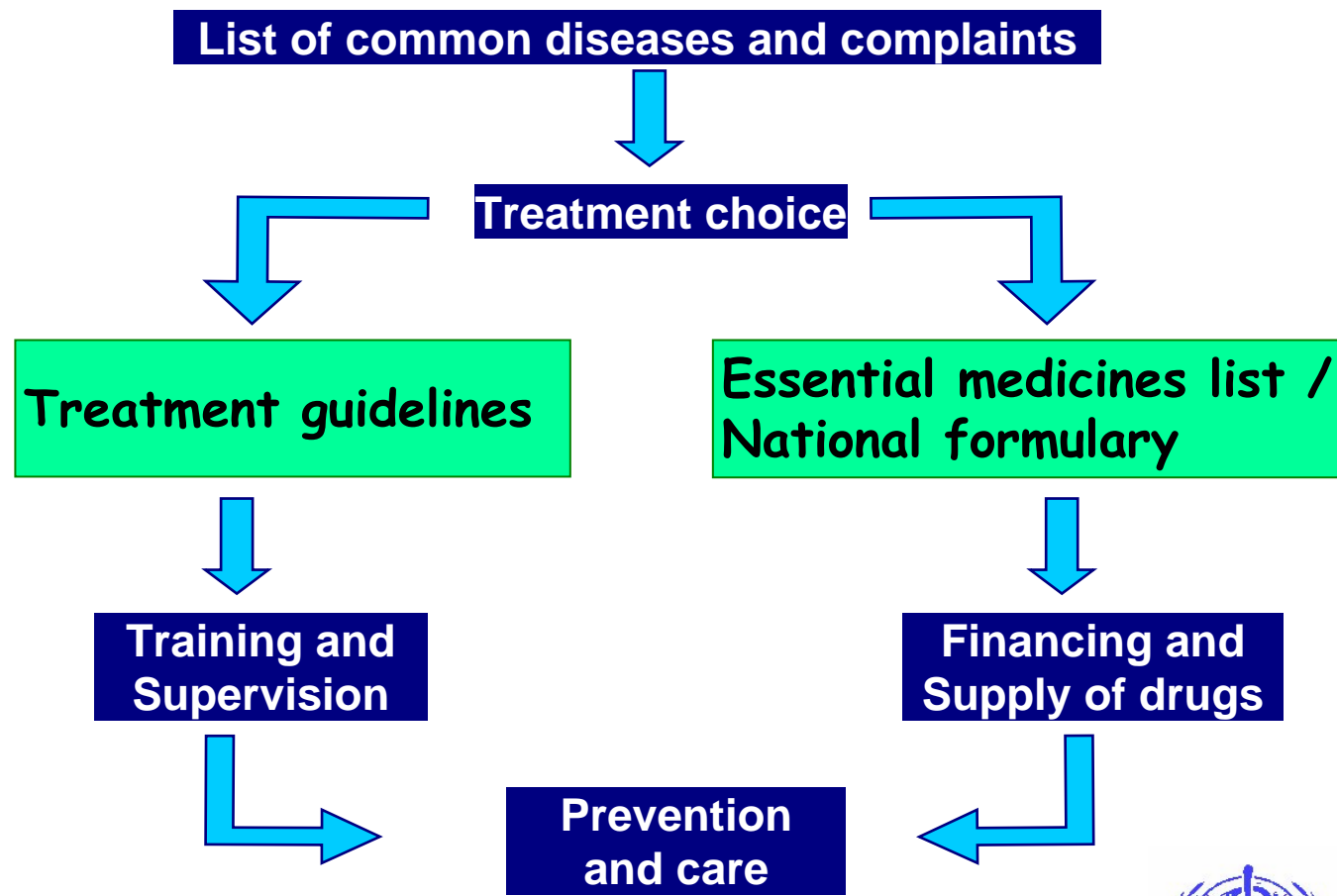
**Selection criteria:** Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness

**Purpose:** Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.

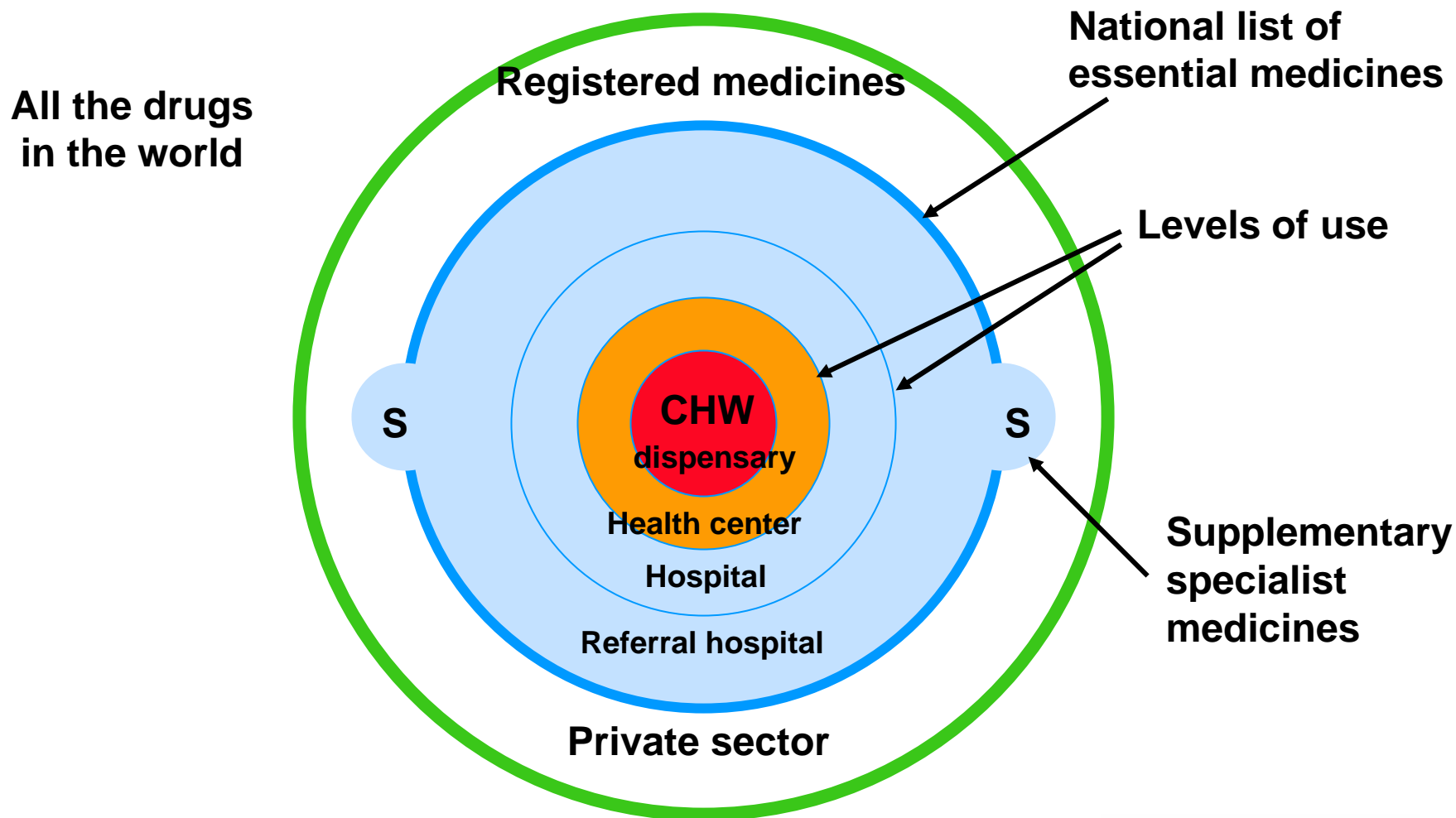
**Implementation:** The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.



# Clinical guidelines and a list of essential medicines lead to better prevention and care



# The Essential Medicines Target



## Use of the WHO Model List of Essential Drugs

- **156 countries** have a national list of essential drugs, of which 81% have been updated in the last 5 years
- Major international **agencies** (UNICEF, UNHCR, IDA) base their catalogue on the WHO Model List
- **Sub-sets**: UN list of recommended essential drugs for emergency relief (85 drugs); interagency New Emergency Health Kit (55 drugs for 10,000 consultations)
- **Normative tools**: WHO Model Formulary, International Pharmacopoea, Basic Quality Tests, and development of reference standards follow the WHO Model List



## Example of challenge:

### New essential drugs are expensive

Antibiotics for gonorrhoea: **50-90x** price of penicillins

Antimalarial drugs: chloroquine \$0.10 per treatment  
coartem® \$3/pp developing country (**30x**)  
malarone® \$40 per dose (**400x**)

Antituberculosis: \$11 for DOTS vs \$250 for MDR (**25x**)

Antiretrovirals: \$300/year; but 38 countries with  
a drug budget <\$2 pp/year





## Model process (1):

# Seven steps to get a new medicine on the WHO Model List of Essential Drugs

1. Identification of public-health need for a medicine
2. Development of the medicine; phase I - II - III trials
3. Regulatory approval in a number of countries
  - > Effective and safe medicine on the market
4. More experience under different field circumstances; post-marketing surveillance
5. Price indication for public sector use
6. Review by WHO disease programme; define comparative effectiveness and safety in real-life situations, comparative cost-effectiveness and public health relevance
  - > Medicine included in WHO treatment guideline
7. Submission to WHO Expert Committee on Essential Drugs
  - > Medicine included in WHO Model List



## Model process (2):

### Link to Guidelines for Guidelines

(approved by WHO Cabinet in January 2001)

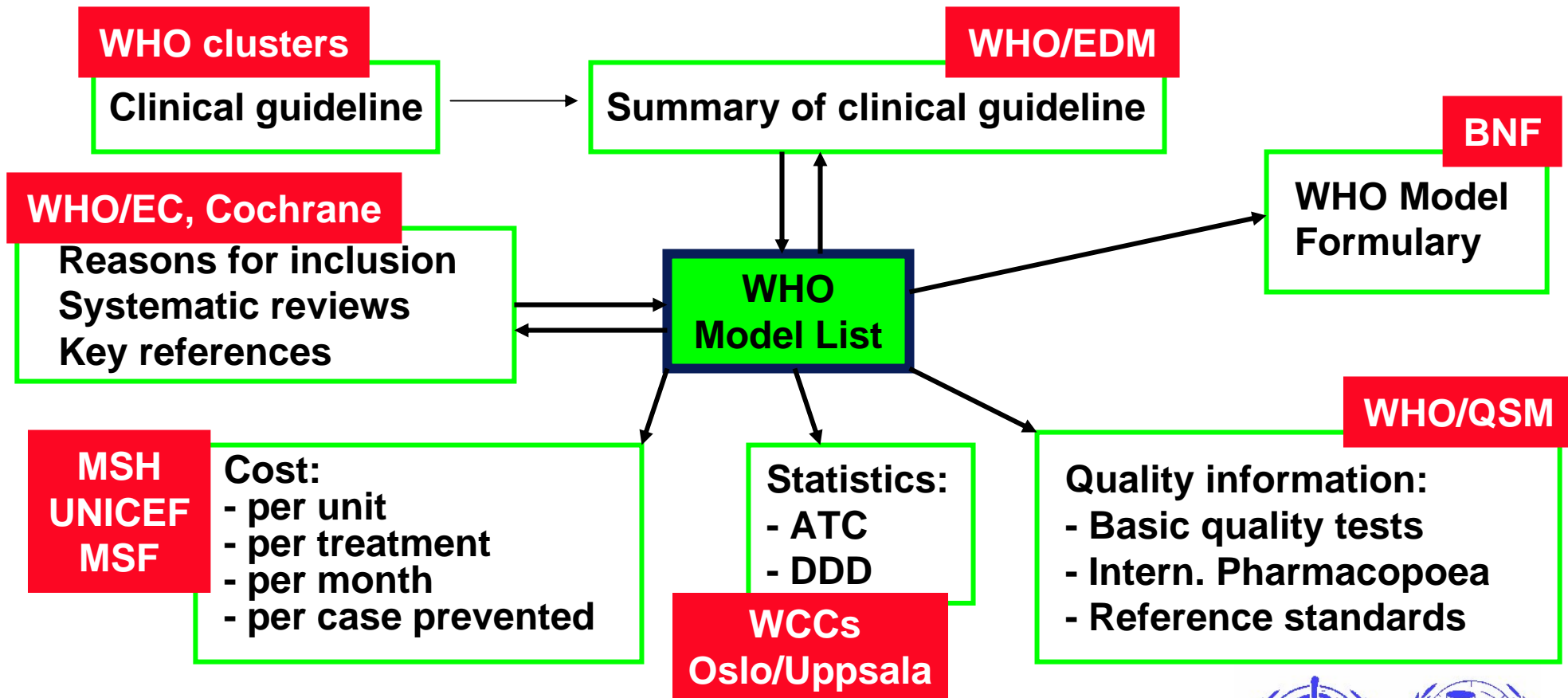
## Systematic and transparent process

- Guideline development group with wide representation
- Careful consideration of conflict of interest
- Systematic computer search for evidence
- Evaluation of strength of evidence
- Systematic cost-effectiveness analysis
- **for WHO: evaluation of public health considerations**
- Graded recommendations with linked references
- External review of draft recommendations
- If there is insufficient evidence: consensus expert opinion

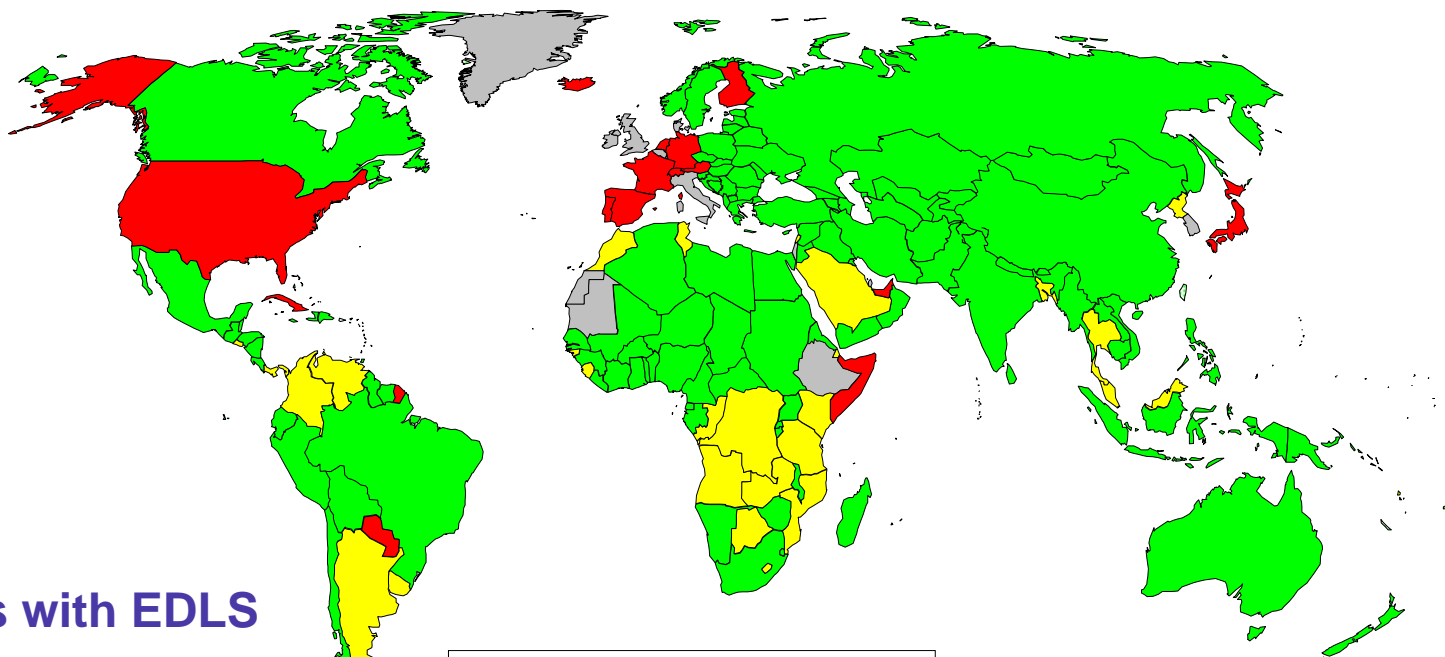


# WHO Essential Medicines Library

## Combining information from various partners



# Number of countries with a national list of essential medicines

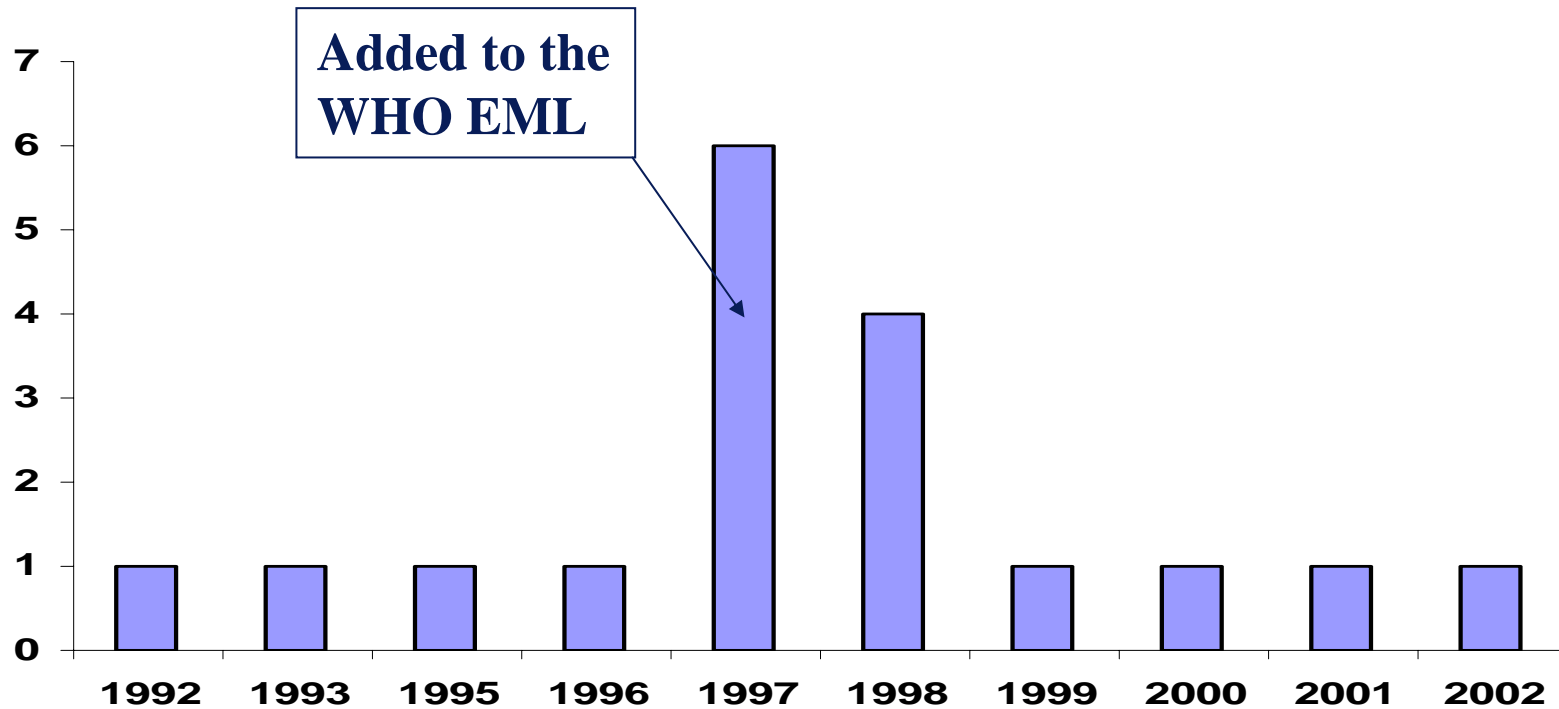


156 countries with EDLS  
 1/3 within 2 years  
 3/4 within 5 years

National Essential Drugs List	
<span style="color: green;">■</span>	< 5 years (127)
<span style="color: yellow;">■</span>	> 5 years (29)
<span style="color: red;">■</span>	No NEDL (19)
<span style="color: grey;">■</span>	Unknown (16)

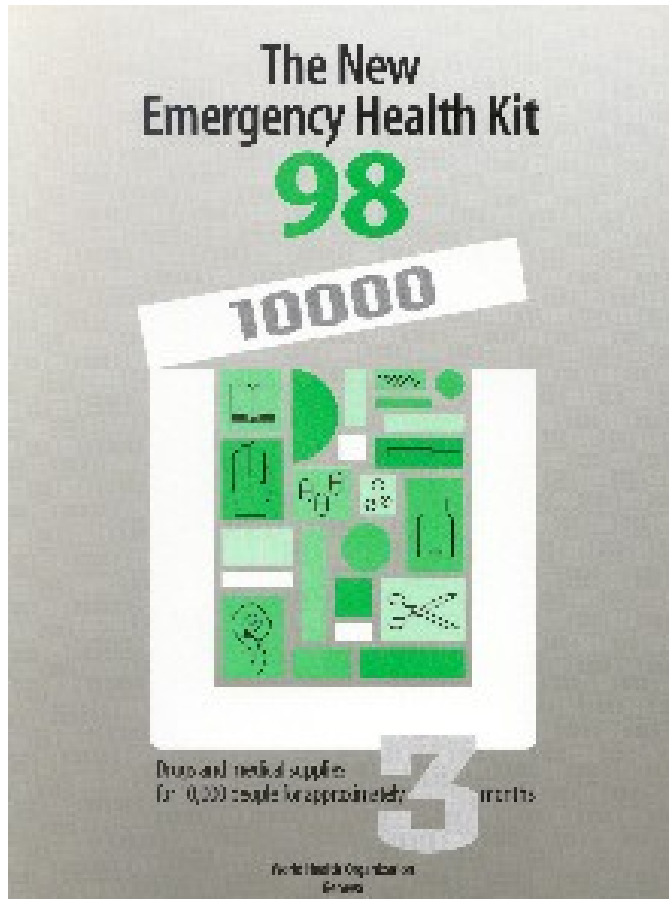


# Time series: Inclusion of **zidovudine** in 19 of 112 national lists reviewed



# The New Emergency Health Kit

1984, 1990, 1998



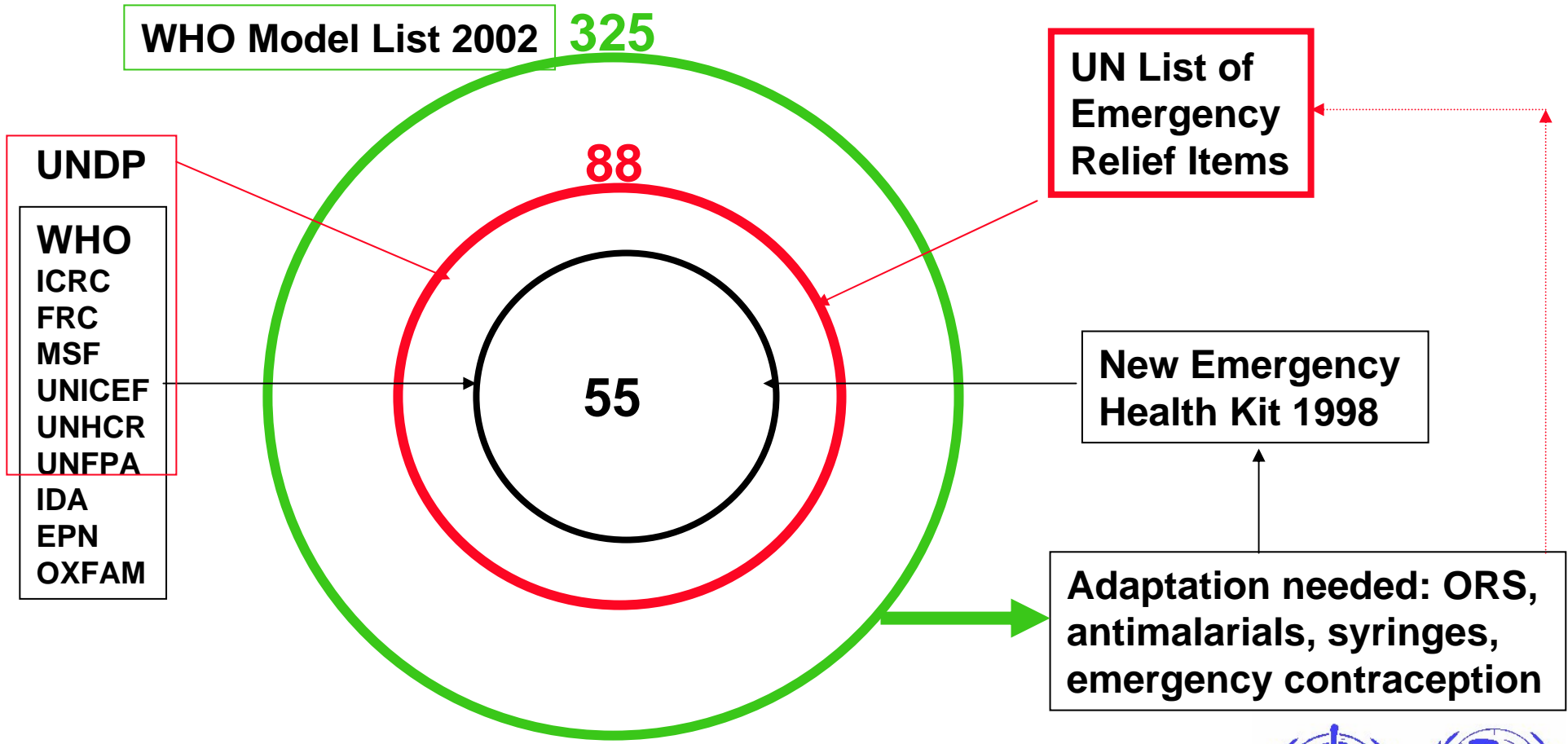
**Essential medicines and supplies for 10,000 people for three months**



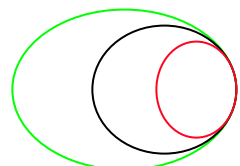
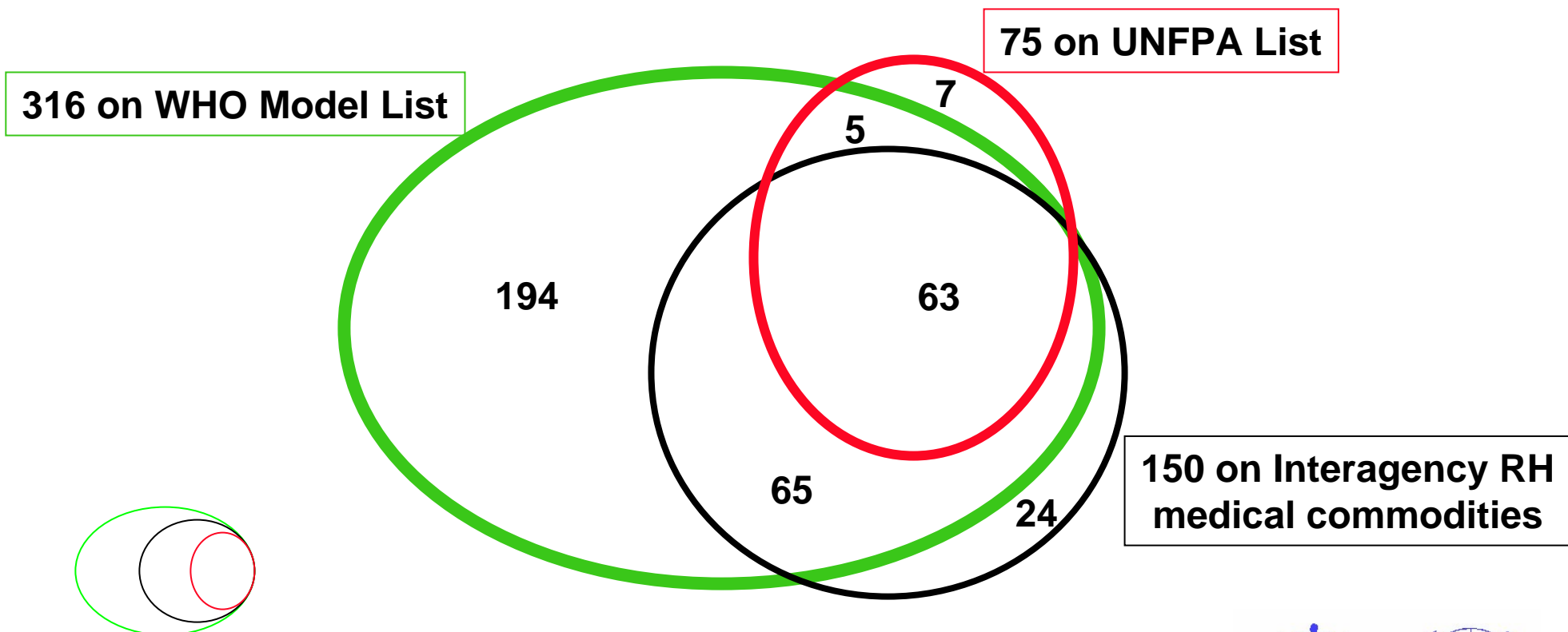
**Consensus between WHO, UNICEF, UNHCR, UNFPA, Red Cross, MSF, OXFAM, missions, IDA**



# The perfect onion: Selection of emergency relief items



# The not-so-perfect onion: Essential medicines for Reproductive Health: Discrepancies in international RH lists (2003)



EM for RH 16

Department of Essential Drugs and Medicines Policy





# First comparison between lists (1): Seems to have been forgotten on R

	U	R	E
ethanol	X		X
hydrochlorothiazide*	X	*	X
norethisterone enantate	X		X
retinol	X		X

\*furosemide on R

U= UNFPA list; R=Interagency list; E= WHO Model List



## First comparison between lists (2):

### Alternative medicine preferred on WHO EML

	U	R	E
clotrimazole	x	x	miconazole
zalcitabine, delavirdine, amprenavir		x	see ARV guide
dephenylhydramine		x	promethazine
itraconazole, ketoconazole		x	fluconazole
labetalol		x	atenolol
magnesium trisilicate, sodium citrate		x	alum.hydroxide
tinidazole		x	metronidazole
ritodrine, terbutaline		x	salbutamol
methylergometrine		x	ergometrine



## First comparison between lists (3): (Recently) deleted from the Model List

	U	R	E
spermicides (removed in 2003)	x		
contraceptive foams/gels		x	
Pethidine (removed in 2003)		x	
iron dextran (removed in 2003)		x	
misoprostol (added in 2005)		x	



# To include or not to include?

## Need for systematic review and submission to WHO Expert Committee 2005

	U	R	E
levonorgestrel-IUDs	x		no
norethisterone enantate + valerate	x		
oestradiol cyprionate + med.prog.acetate	x		
indometacin (tocolytic)		x	
cefazolin (geneal surgical prophylaxis)		x	
cefixime (gonorrhoea)		x	yes
prostaglandins		x	yes
subdermal contraceptive implants		x	no



## Essential Medicines for Reproductive Health: Current status of joint review project

1. Annotated list all WHO resource materials and standard treatment guidelines for RH medicines; link with essential medicines list(s); discrepancies identified
2. Summary of available Cochrane reviews and other evidence for all RH medicines
3. List of medicines for which additional evidence is needed; reviews performed and submitted to 14<sup>th</sup> Expert Committee

**Next steps: International consensus on essential RH medicines; standardization of essential non-drug RH items; guideline for inclusion of RH items in national lists of essential medicines**





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