

15th
GENERAL MEMBERSHIP MEETING
of the **REPRODUCTIVE HEALTH**
SUPPLIES COALITION
20-24 OCTOBER
MEXICO CITY

mexico
2004-2014
REPRODUCTIVE HEALTH
SUPPLIES COALITION



NEW AND UNDERUSED REPRODUCTIVE HEALTH TECHNOLOGIES AS ESSENTIAL MEDICINES

RHSC NURHT Caucus
Mexico City, Mexico



AVAILABILITY



QUALITY



EQUITY



CHOICE

MEETING OUTLINE

- What are the New and Underused Reproductive Health Technologies
- The WHO Model List of Essential Medicines (5 minutes)
- Discussion of EML criteria and where NURHTs belong (15 minutes)
- Overview of member efforts/data collected on EMLs (5 minutes)
- Potential next steps/objectives (15 minutes)
 - Advocating for EMLs
 - Other ideas

What are the new and underused RHTs?

Contraceptive Implants

CycleBeads®

Diaphragm

Emergency contraceptive pills

Female condom

Levonorgestrel Intrauterine
System

Magnesium sulfate

Manual vacuum aspiration

Mifepristone and misoprostol

Misoprostol

Oxytocin

Pregnancy tests for family
planning

Progesterone vaginal ring

The WHO Model List of Essential Medicines

“Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford.”

- WHO Technical Report Series, No. 895, 2000

Model List is updated and revised every two years by the WHO Expert Committee on Selection and Use of Medicines (currently 18th version)

Core: Minimum medicine needs for a basic health-care system

Complementary: Essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed

Procedure: 2001

http://apps.who.int/gb/archive/pdf_files/EB109/eeb1098.pdf?ua=1

PROCESS FOR APPLICATIONS

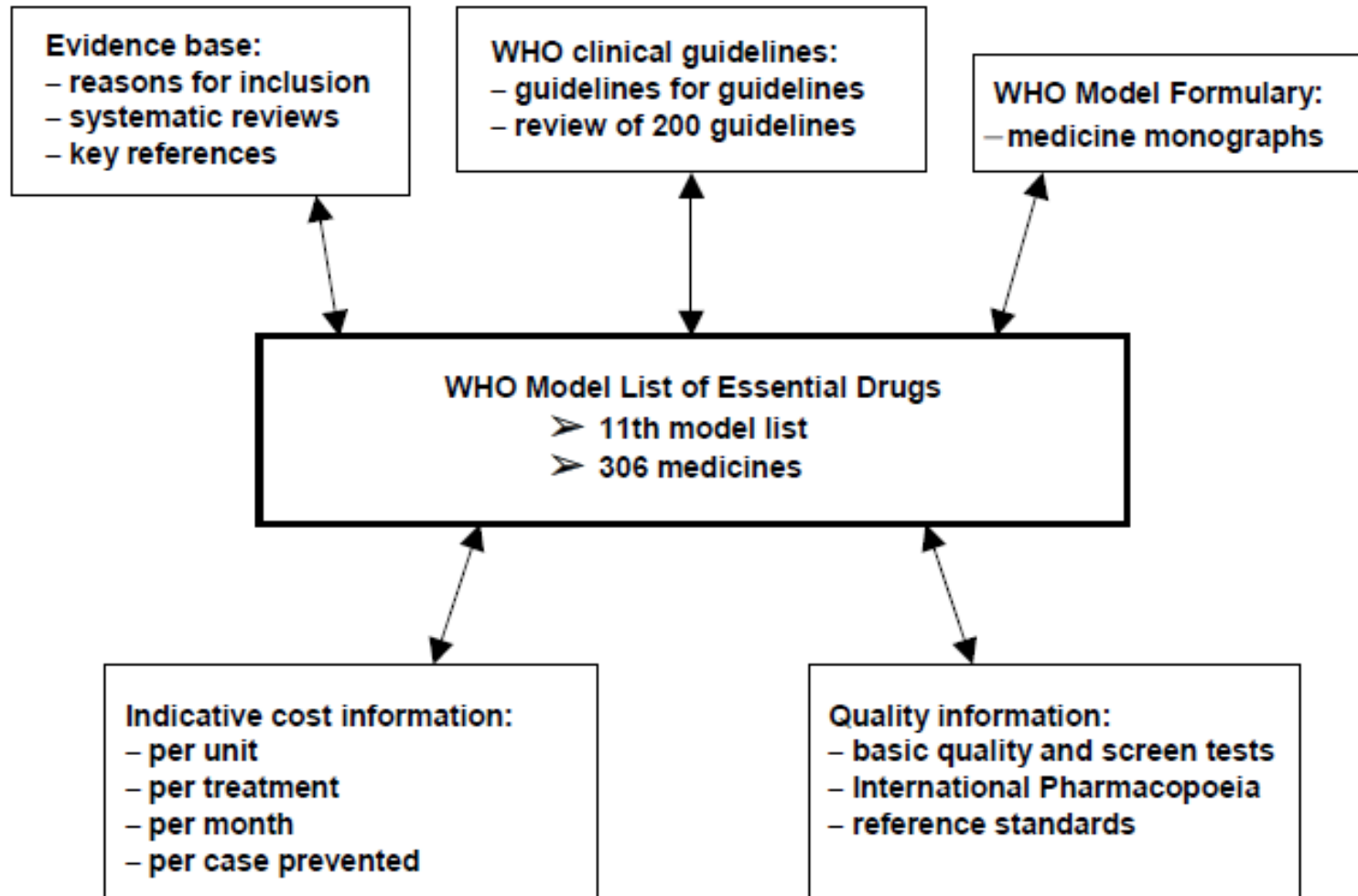
Submitted by or through relevant departments in WHO to the Expert Committee (four months prior to Committee Meeting)

1. Summary statement of the **proposal for inclusion**
2. Name of the **focal point in WHO** submitting the application
3. Name of the **organization(s) supporting the application**
4. Information supporting the **public health relevance** (disease burden, current use, target population)
5. **Treatment details** (dosage, duration; refs to WHO and other clinical guidelines; need for special diagnostic or treatment facilities and skills)
6. Summary of **comparative effectiveness** in a variety of clinical settings
7. Summary of comparative evidence on **safety**
8. Summary of available data on **comparative cost and cost-effectiveness** within the pharmacological class or therapeutic group
9. Summary of **regulatory status** of the medicine
10. Availability of **pharmacopoeial standards**
11. Proposed **text for the WHO Model Formulary**

REVIEW PROCESS

1. Secretary checks the application for completeness
2. Application summary posted on WHO website
3. Specialist assessment(s) on comparative efficacy, safety and cost-effectiveness (with relevant departments in WHO)
4. Assessment outcomes summarized by an expert; formulates a draft recommendation for the Expert Committee; invited to attend the next meeting as “presenter”
5. The draft recommendation and Model Formulary text reviewed by WHO and members of expert advisory panels; posted on the WHO website for comments, for a minimum of 30 days
6. Presenter reviews the comments and formulates a final text for consideration
7. Expert Committee reviews and adopts the application as a recommendation to the Director-General
 - **Results posted to WHO website**
 - **WHO Technical Report Series**

WHO MEDICINES LIBRARY



CRITERIA – NURHTs on the MODEL LIST?

DEFINITION

“Satisfy the health care needs of the majority of the population”

FACTORS

- disease burden
- safety
- efficacy
- comparative cost effectiveness (total treatment and medicines cost)
- stability
- need for special facilities (diagnosis/treatment)
- pharmacokinetics

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Progesterone vaginal ring

CURRENT STATUS OF NURHTS ON MODEL LIST

TECHNOLOGY	WHO MODEL LIST OF ESSENTIAL MEDICINES	WHO PQ ELIGIBLE	TRT WORK*
Contraceptive Implants	18.3.5 Implantable contraceptives levonorgestrel-releasing implant; Two-rod levonorgestrel-releasing implant, each rod containing 75mg of levonorgestrel (150 mg total).	YES	NO
CycleBeads®	NO	NO	NO
Diaphragm	18.3.4 Barrier methods; diaphragms	?	NO
EC pills	18.3.1 Oral hormonal contraceptives levonorgestrel; Tablet: 30 micrograms; 750 micrograms (pack of two); 1.5 mg.	YES	NO
Female condom	18.3.4 Barrier methods; condoms	YES	NO
Levonorgestrel IUS	NO	NO	NO
Magnesium sulfate	5. ANTICONVULSANTS/ANTIEPILEPTICS magnesium sulfate*; Injection: 500mg/ml in 2-ml ampoule; 500mg/ml in 10-ml ampoule.; *For use in eclampsia and severe pre-eclampsia and not for other convulsant disorders.	YES	YES
MVA	NO	NO	NO
Mifepristone and misoprostol	22.1 Oxytocics Complementary List; mifepristone*-misoprostol* <u>Where permitted under national law and where culturally acceptable</u> Tablet 200mg – tablet 200 micrograms. *Requires close medical supervision	YES	NO
Misoprostol	22.1 Oxytocics misoprostol; Tablet: 200 micrograms.* *For management of incomplete abortion and miscarriage, and for prevention of postpartum haemorrhage where oxytocin is not available or cannot be safely used. Vaginal tablet: 25micrograms.; *Only for use for induction of labour where appropriate facilities are available.	YES	YES (PPH pvt)
Oxytocin	22.1 Oxytocics oxytocin; Injection: 10 IU in 1-ml	YES	YES
Pregnancy tests for FP	NO	NO	NO
Progesterone vaginal ring	NO	NO	NO

NURHTS AND EMLS: QUESTIONS (1)

WHO MODEL LIST

- What NURHTs are left to be added?

CycleBeads; LNG IUS; pregnancy tests; progesterone vaginal ring

- Which ones satisfy the criteria?

“Satisfy the health care needs of the majority of the population”

- Is the current evidence sufficient for a successful application?
- If not, how to generate?
- Who at the WHO advocates for/supports their inclusion?
- Which organization(s) file the applications?

NURHTS AND EMLS: QUESTIONS (2)

COUNTRY EMLS

- What products are under-represented?

Implants, EC pills, female condom, mifepristone+ misoprostol, misoprostol (oxytocin, magnesium sulfate)

- What is the process of adding to EMLS?
- Who takes responsibility for advocating for their addition?

WHAT'S BEEN DONE AND WHAT IS THERE DO TO?

- Understanding relationship between EML and procurement in countries
- Understanding processes and information required
- Advocacy for product inclusion
- Applications for appropriate products
- OTHERS?