NEW AND UNDERUSED REPRODUCTIVE HEALTH TECHNOLOGIES AS ESSENTIAL MEDICINES

RHSC NURHT Caucus
Mexico City, Mexico
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?

<table>
<thead>
<tr>
<th>Contraceptive Implants</th>
<th>Manual vacuum aspiration</th>
</tr>
</thead>
<tbody>
<tr>
<td>CycleBeads®</td>
<td>Mifepristone and misoprostol</td>
</tr>
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<td>Misoprostol</td>
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<td>Progesterone vaginal ring</td>
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<td></td>
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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.”


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 pharmacopoieal 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

- Evidence base:
  - reasons for inclusion
  - systematic reviews
  - key references

- WHO clinical guidelines:
  - guidelines for guidelines
  - review of 200 guidelines

- WHO Model Formulary:
  - medicine monographs

WHO Model List of Essential Drugs
- 11th model list
- 306 medicines

Indicative cost information:
- per unit
- per treatment
- per month
- per case prevented

Quality information:
- basic quality and screen tests
- International Pharmacopoeia
- reference standards
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

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
## CURRENT STATUS OF NURHTS ON MODEL LIST

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