



make medicines **Child Size**

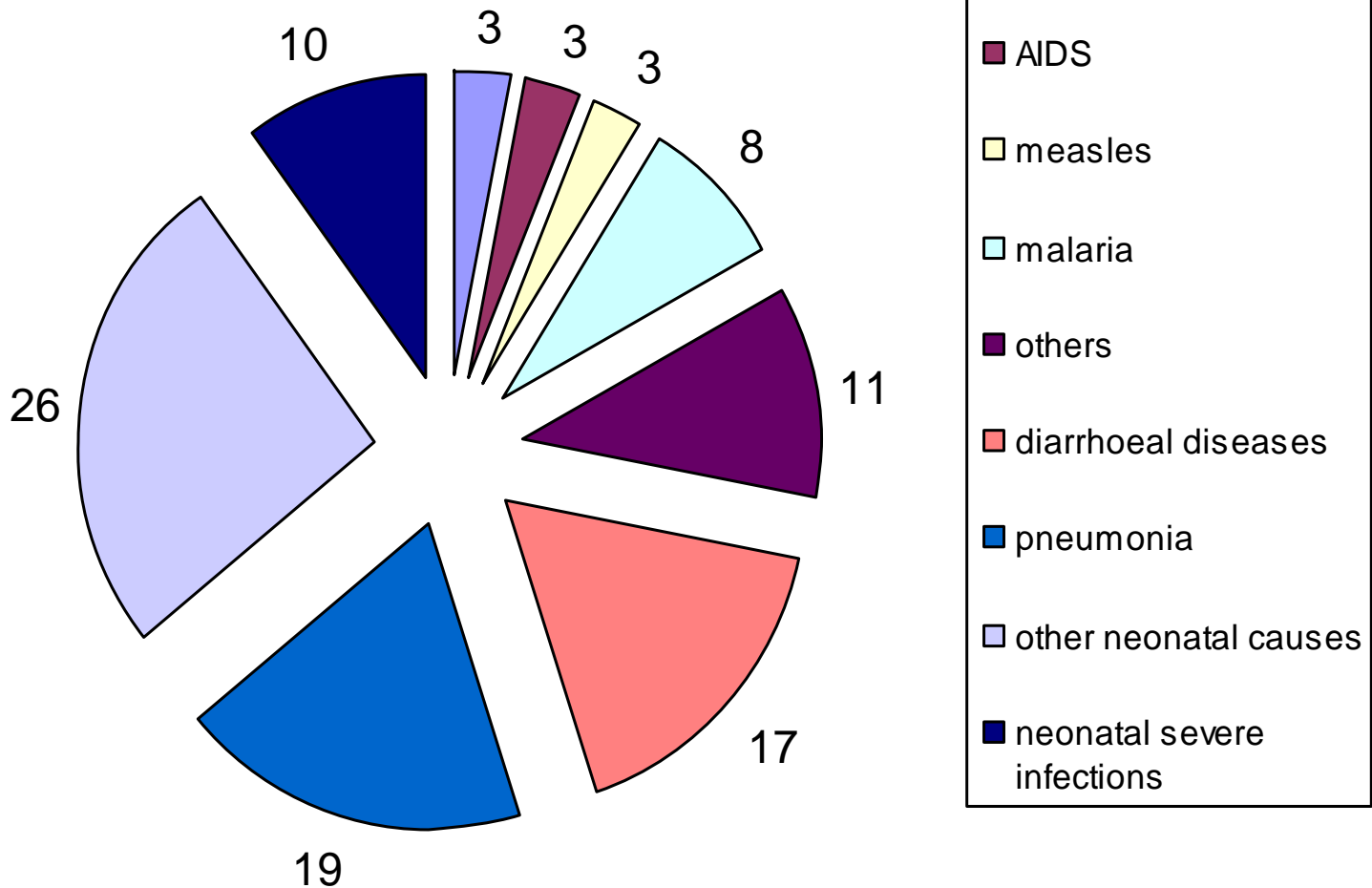
ESSENTIAL MEDICINES FOR CHILDREN

Dr Suzanne Hill
Presented by Adriana Velazquez
HTAI
Rio Janeiro
June 2011



**World Health
Organization**

Causes of death in under 5s



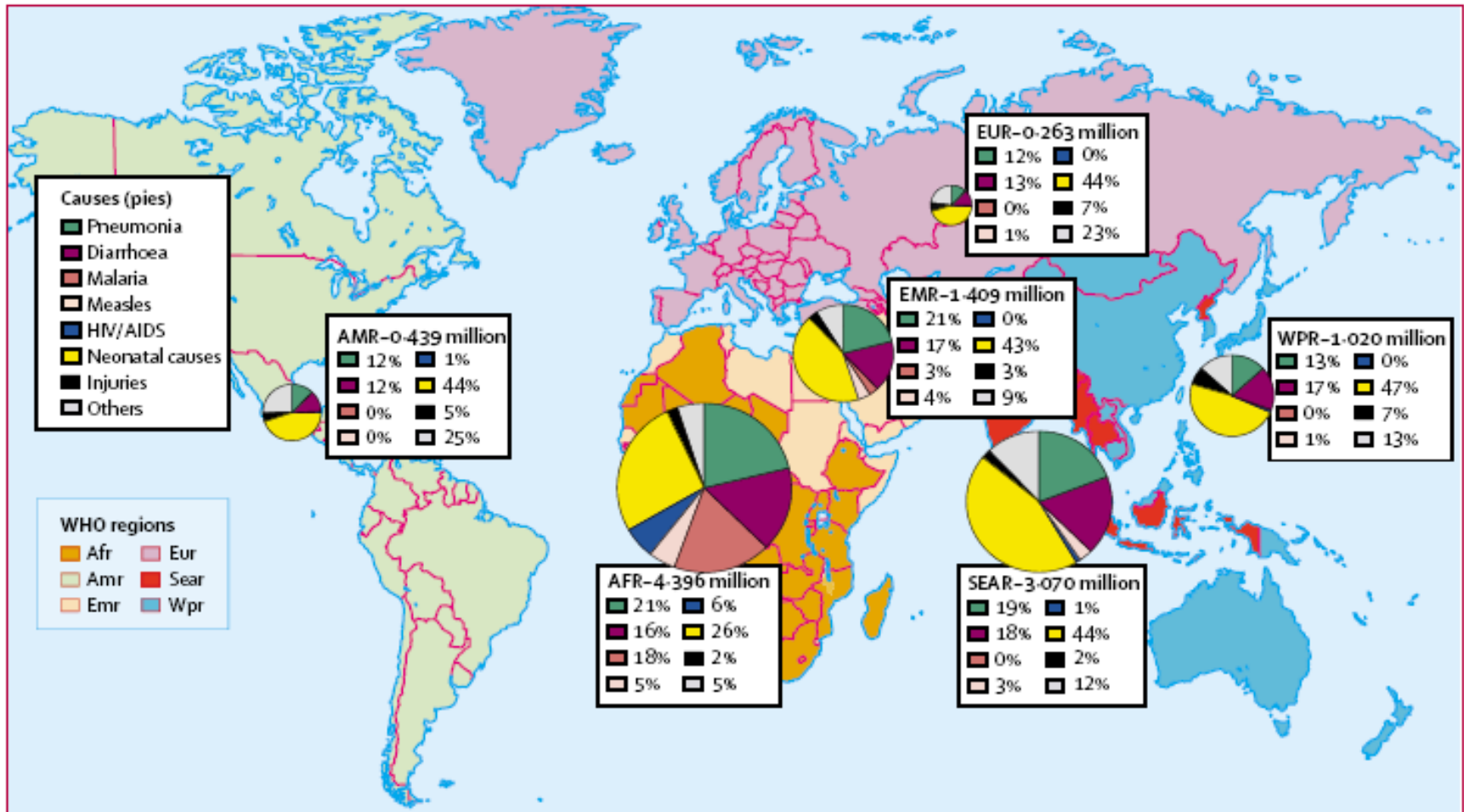


Figure 3: Number of deaths in children younger than age 5 years and their distribution by cause for the six WHO regions (yearly average for 2000-03). Size of circle represents number of deaths in region. Afr=Africa. Amr=Americas. Emr=Eastern Mediterranean. Eur=Europe. Sear=Southeast Asia. Wpr=Western Pacific.



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17th Expert Committee on the Selection and Use of Essential Medicines

The 17th Expert Committee on the Selection and Use of Essential Medicines was held from 23 to 27 March 2009.

Applications for inclusion, change or deletion of a medicine in the Model List of Essential Medicines were sent to the Secretary of the Committee whose address is below.

The Secretary of the 17th Expert Committee on the Selection and Use of Essential Medicines
Medicine Access and Rational Use (MAR)
Department of Essential Medicines and Pharmaceutical Policies (EMP)
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27
Switzerland

Public comments, including letters of support on the applications submitted to: emlsecretariat@who.int have been then published on the web.

The documents produced by the 17th Expert Committee on the Selection and Use of Essential Medicines are now available:

- WHO Technical Report Series -- The Selection and Use of Essential Medicines, March 2009 [pdf 997kb]
- 16th WHO Model List of Essential Medicines, March 2009 [pdf 432kb]
- Second WHO Model List of Essential Medicines for Children, March 2009 [pdf 418kb]

USEFUL DOCUMENTS

[16th WHO Model List of Essential Medicines \[pdf 432kb\]](#)

[Second WHO Model List of Essential Medicines for Children](#)



[WHO Technical Report Series 950 Read more... \[pdf 844kb\]](#)



[WHO Technical Report Series 946](#)





What is the problem?

- **Children are therapeutic orphans**
 - Lack of appropriate clinical trials
 - Lack of licensed medicines
 - Lack of formulations
 - Lack of information
- **Initiatives so far concentrated on:**
 - Developed country regulatory structures (eg FDA, EMEA)
 - Developed country drug information (eg BNF- C)
 - HIV (eg new public private partnership)

Quantitative study in 14 African countries

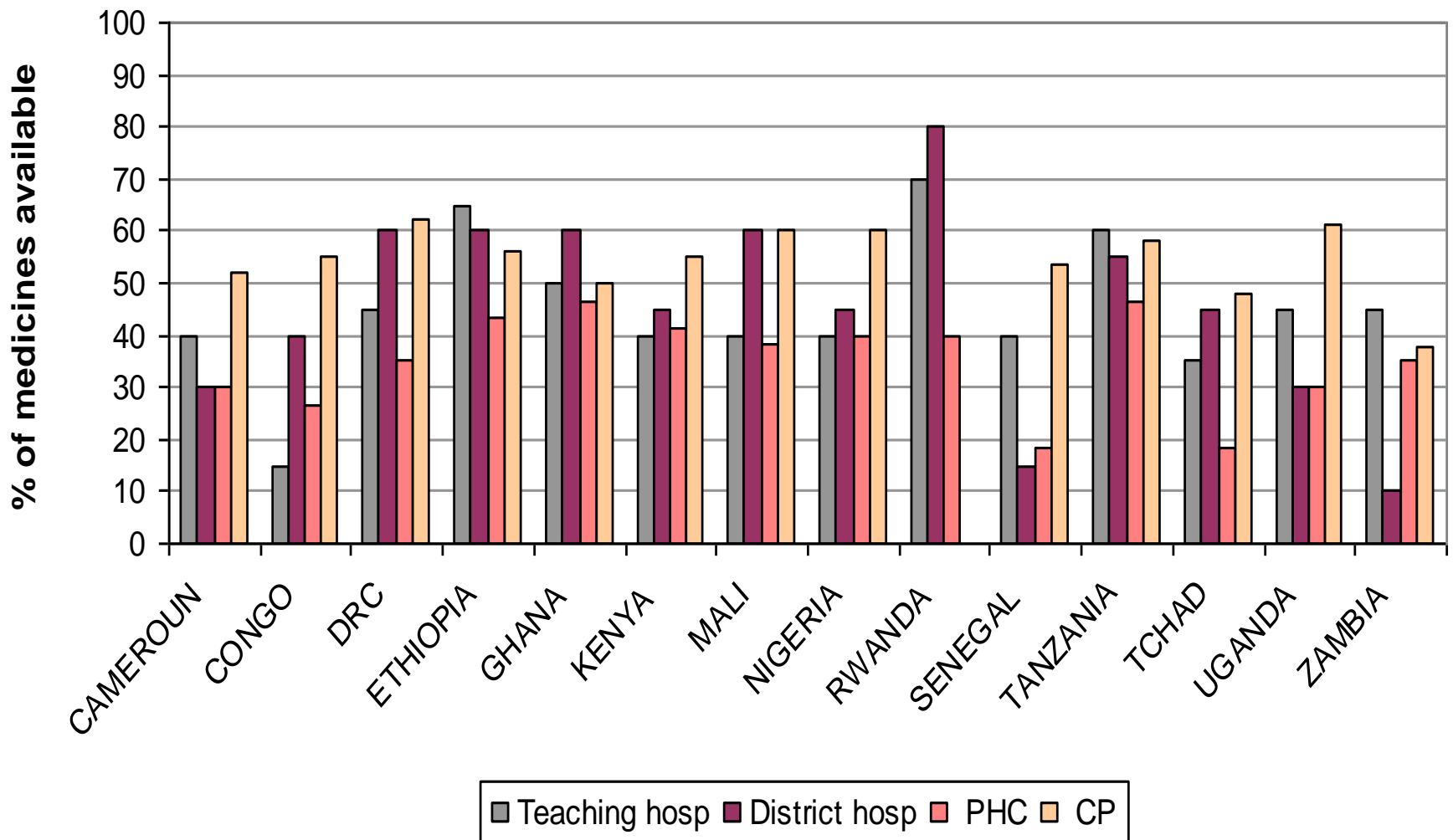
■ Sampling

- Adapted methods of HAI/WHO pricing surveys
- Limited to capital cities only
- 12 facilities surveyed: CMS (1) NGO facility (1) Teaching hospital (1) District hospital (1) Primary health care clinics (3) Community pharmacies (5)

■ Questions asked

- Are listed medicines included in national EML and STGs
- Are listed medicines available for supply in the facility on the day of the survey and what is the cost to the patient of the cheapest product available (branded or generic product)

Proportion of medicines available in Public and Private sector outlets



Obvious gaps

- **Essential medicines list – paediatrics**
- **Formulations eg fixed dose combinations for malaria, TB**
- **Prescribing information**
- **Market incentives for appropriate drug development**
- **International regulatory standards, including quality**
- **International safety monitoring and post-marketing surveillance**



Plan

- **Work on a global project to make paediatric medicines a priority:**
 - **Develop Model List of Essential Medicines for children and update 2007-2008**
 - **Update treatment guidelines**
 - **Develop paediatric prescribing information – a formulary**
 - **Collaborate with regulatory authorities to encourage appropriate drug development and approval processes in all regulatory authorities**
 - **Identify ideal paediatric dosage forms**
 - **Develop quality standards for paediatric medicines**
 - **Develop a system for enhancing safety monitoring of medicines in children**
 - **Provide guidance on procurement and supply of paediatric medicines**

Paediatric formulation issues

- Technical difficulties of manufacturing
- Storage and preparation
- Impact of various climates
- Taste of the medication
- Local factors and practice

Specific issues

■ Liquids

- Short shelf lives
- Often require refrigeration
- Bulky and heavy
(issue for storage and transport)

■ Powders for suspension

- Mixed correctly with sterile fluids
- Affected by humidity

■ Chewable tablet

- Tolerated by children two years and older
- Limited dose variation

Key issues

- **Second list of essential medicines for children**
 - **Review and confirmation of medicines on the List**
 - **Additions proposed (Section 5 of report)**
 - **Deletions (Section 5)**
 - **New sections:**
 - Palliative care
 - Ear Nose and Throat
 - Medicines for use in neonates

Progress

- **Essential medicines list – paediatrics**
- **Formulations eg fixed dose combinations for malaria, TB**
- **Prescribing information**
- **Market incentives for appropriate drug development**
- **International regulatory standards, including quality**
- **International safety monitoring and post-marketing surveillance**

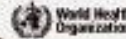


Contribution from industry

- **Not just liquids..**
 - Experience with innovative dosage forms
 - Capacity in development
 - Linkages with academic groups
- **Finding existing data**
 - Kinetic studies
 - Adverse event data
 - Younger age groups
- **Quality clinical trials**
 - GCP and ethics committee capacity
 - Registration and reporting
- **Product development and registration**



30 Years of Essential Medicines



Where is my essential medicine?

¿Dónde está mi medicamento esencial?

Et moi?



**World Health
Organization**