The Challenge and Exploration of Children’s Access to Medicines: Experience of China

Lingli Zhang
West China Second University Hospital, Sichuan University, China
Chinese Evidence-based Medical Center/Chinese Cochrane Center
INRUD, China
BRICS Medicines Alliance
The MDGs and challenge of children’s access to medicines

The exploration and practice of China
In 2000, 8 Millennium Development Goals were agreed by country leaders from 189 countries at the UN Millennium Summit.

The 4th Goal: Reduce child mortality by two thirds.

The progress and gap of the MDGs: Goal 4

The MDGs and challenge of children’s access to medicines

WHO proposes

- Reaching the MDGs on reducing child mortality requires universal coverage with effective and affordable interventions
- Medicine is one of the most important measures
- Rational medicine treatment and prevention could avoid 8.1 million children under 5 years old from death each year

The current situation of children’s access to medicines

- **Lack of medicines exclusive for children:** Many medicines for priority diseases are not developed for children; and when they are, they are not reaching the children who need them most.

- **Lack of children appropriate dosages and specifications:** Medical staffs and guardians of children tend to use reduced-dose adult medicines, as well as crush tablets or dissolve capsules in water to prepare medicines for children.

- **Lack of cost-effectiveness of medicines for children:** The few existing paediatric fixed dose combinations developed for children are generally three times more expensive than the adult dosage form.

- **China for example:** A survey of medicines used in pediatrics in 15 hospitals during 2011-2013. 
  
  Total: 1098, Medicines exclusive for children: 45, accounting for 4.1%.

### National actions

- 2011 CFDA: Survey on the suggestion of legislation for children-safe packaging of medicines
- 2011 MOH: Strengthen the Management of Clinical Medication in Maternal and Children
- 2012 MOH: Established the new INRUD China Core Centre led by the Director of Medical Administration of MOH, included the investigation on the management of vulnerable populations.
- 2012 MOH: Healthy China 2020
- 2013 MOH: China National Formulation for Children
- 2014 MOH: Proposed “Access to Essential Medicines” Proposal to WHA and passed by WHA
- 2014 Six Ministries: Several Opinions on Security of Medications in Children
- 2014 MOH: Established the Surveillance Network of Antibiotics Use in Children
- 2015 MOH: Proposed “Promoting the Safety and Accessibility of Children's Medication” Proposal to WHA
- 2015 the State Council: “Guidance Opinions about Improving the Centralized Procurement of Drugs in Public Hospitals”, the procurement of drug dosages forms and specifications should considerate children’s medication need

### Multi-department coordination

- 2012 CPPCC,CFDA,MOH and the State Administration of TCM: Symposium on Medication in Children
- 2014 Six Ministries: Several Opinions on Security of Medications in Children
- 2011 Sichuan Provincial Health Department: Supplement Medicines Additional Catalogue of Sichuan Province in Primary Care to NEML
- 2012 MOH: National Essential Medicine List added medicines, dosage forms and specifications for children
- 2013 CFDA: Opinions on Deepening the Reform of Medicine Evaluation and Approval, Further Encouraging Medicine Innovation

### Policy support

- 2014 MOH: Survey on dosage and administration of children’s essential medicines
- 2014 MOH: Investigation on priorly encouraging the development of children appropriate dosages and specifications
- 2014 MOH: Developed China’s first national medicines list for children require fast review, using evidence-based method
- 2014 CFDA: Guiding Principles on Research Techniques of Pediatric Population's Pharmacokinetics
- 2014 CFDA: Technical Guidelines for Clinical Trials of Pediatric Medicines
- 2014 MOH: Major Project on Development and Production of New Medicines: children’s diseases
- 2015 MOH: Established Expert Committee on Children’s Medication of MOH
- 2015 MOH: The follow up assessment on the executive progress of the WHO “Access to Essential Medicines” resolution

### Technical Support

- 2015 MOH: Assessment of the Implementation of the WHA resolution

### Continuous follow-up and improvement
Access to essential medicines

The Sixty-seventh World Health Assembly,

Having considered the report on access to essential medicines;¹

Noting that WHO’s definition of an essential medicine² contains the following elements: “Essential medicines are those that satisfy the priority health care needs of the population” and “Essential medicines are selected with due regard to their public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness”;

Recalling resolution WHA28.66 on prophylactic and therapeutic substances that relates to the formulation and implementation of medicines policies and pharmaceutical strategies; the Declaration of Alma-Ata in 1978 that recognized the provision of essential medicines as one of the pillars of primary health care, and subsequent resolutions in relation to essential medicines, such as resolution WHA54.11 on the WHO medicines strategy, WHA58.27 on improving the containment of antimicrobial resistance, WHA60.16 on progress in the rational use of medicines, WHA60.20 on better action for children, WHA60.29 on health technologies, WHA61.21 on the global strategy and plan of action on public health, innovation and intellectual property, and WHA64.9 on sustainable health financing structures and universal coverage, as well as WHA66.10 in which the Health Assembly endorsed the WHO global action plan for the prevention and control of noncommunicable diseases 2013–2020, and which includes Target (9) on the availability of essential medicines required to treat noncommunicable diseases;

Bearing in mind that the WHO medicines strategy, as set out in the Twelfth General Programme of Work 2014–2019, is based on the principles of evidence-based selection of a limited range of medicines, efficient procurement and distribution systems, affordable prices, and the rational use of medicines in order to promote better management and greater availability of medicines, more cost-effective use of health resources, and higher quality health care;


● 2014, Security of Medications in Children

Drug Policy and Essential Medicine System Department of National Health and Family Planning Commission

Jointly issued by the MOH, the National Development and Reform Commission, the Ministry of Industry and Information Technology, the Ministry of Human Resources and Social Security, CFDA and the State Administration of TCM and focus on encouraging R&D, accelerating application and evaluation, guaranteeing production and supply, improving the rational use of medicines in children

Press conference of China Central Television and China National Radio

18 December 2014

Dear Dr. Liangli Zhang,

I am pleased to invite you to participate in the 2015 Social Forum, which will take place in accordance with Human Rights Council resolution 26/28 entitled “The Social Forum” (copy attached). In this resolution, the Council decided that the next meeting of the Social Forum should focus on access to medicines in the context of the right to health. It requested the High Commissioner to facilitate the participation of ten experts in the 2015 Social Forum to contribute to interactive dialogues and debate, and to assist the Chairperson-Rapporteur as resource persons.
• To develop national EMLc was included in the proposal and was passed
The suggestion of developing China’s essential medicines list for children was passed by MOH

- July 7th, 2015, the 3rd country in the world develops EMLc: China
2015, established Expert Committee on Children’s Medication of MOH, including 5 professional groups:

- **Essential Medicines and Directory of Insured Medicines for Children Working Group**
- **Guidelines for Children’s Medication Working Group**
- **Comprehensive Evaluation for Children’s Medicines Working Group**
- **Training and Publicity of Children’s Medication Working Group**
- **Clinical Trial of Children’s Medicines and Precision Medicine Working Group**

The 1st Plenary Session of MOH Expert Committee on Children’s Medication
• Essential Medicines and Directory of Insured Medicines for Children Working Group
  ➢ Completed the basic medication research for Chinese children, compared the commonly used medicines for Chinese children, China’s national essential medicines and WHO Essential Medicines List for Children, developed the active ingredients list of commonly used medicines for Chinese children
• Guidelines for Children’s Medication Working Group
  By the end of December 2015, developed 10 guidelines
• Training and Publicity of Children’s Medication Working Group
  ➢ Formulated 2016 rational drug use training plan for pediatric pharmacists. 8000 pediatric physicians will complete the training
  ➢ Established popularization alliance of children’s medication with several medias, the working group is compiling the contents, which will be released to the public by the media alliance
● Evaluation of After Effect

- 2015 MOH Bidding Subject: Assessment of the Implementation of the WHA Resolution

Drug Policy and Essential Medicine System Department of MOH

Project 7: The Assessment of the Implementation of the WHA Resolution
2015, China’s National Proposal to the 138th WHO's Executive Board

- The Sustainable Development Goals (SDGs): to end preventable deaths of newborns and children under 5 years of age
- Promoting the Safety and Accessibility of Children's Medication

The 138th WHO's Executive Board

Suggestion on Proposal "Promoting the Safety and Accessibility of Children's Medication"

The 60th World Health Assembly passed the resolution "better medicines for children" in 2007, calling systematic requirements for member states and the Director-General to meet the demand of children's medication. However, by far, the resolution has not been implemented very well. 6.6 million children under the age of 5 died in 2012, many of them died from treatable diseases: pneumonia most common, others including diarrhea, HIV infection, AIDS and malaria. Nearly all (99%) deaths occurred in low and middle income countries. A main factor causing the high morbidity and mortality of children, notably children under 5, is the inaccessibility to quality-assured medicines for children. So
Thanks for your attention

Lingli Zhang, M.D. Ph.D.
Professor and Director of Pharmacy
West China Second University Hospital, Sichuan University
No.20,Section 3, Renmin South Road, Chengdu, Sichuan, 610041, P.R.China
Fax:+86 28 85501012
E-mail: zhanglingli@scu.edu.cn
zhlingli@sina.com
- DALYs (Disability-adjusted life years) of different ages in global