Status of Pediatric Medication and Strategy in China

Beijing Children's Hospital, Capital Medical University

SHEN Kunling
China's GDP could top 61.1 trillion yuan (about 10 trillion dollars) by the end of 2014, making China the world's second-largest economy.
Huge children’s population, steady growth

- Huge base: the sixth national census (2010)
  - 0-6 years: over 100 million, accounting for $\frac{1}{5}$ of the world population of the same age
  - 0-14 years: 222 million, accounting for 16.6% of China’s total population
  - 0-18 years: about 300 million, accounting for 22.5% of China’s total population

  Total US population: 320 million

- Steady growth, especially after the release of two-child policy
  - New-born population of about 20 million per year
  - New birth rate: 1 baby/4.15 seconds
  - The number of births in 2010 was 3 times the number 8 years ago
Remarkable Improvement of Health Level of Children

- MDG 4 called for a two-thirds reduction in the under-5 mortality rate between 1990 and 2015.
- Mortality of infants and children under 5 decreased by 82.3% and 80.8% respectively, from 50.2‰ and 61.0‰ in 1991 to 8.9‰ and 11.7‰ in 2014. China reached MDG4 target ahead of time.
Infant Mortality in China During 1991-2014

Year

0
10
20
30
40
50
60
‰

Overall
Urban Area
Rural Area
Children are not the simply “mini-adults”. Developmental Changes in Physiologic Factors will Influence Drug Disposition in Infants, Children, and Adolescents.
“The shortage of medication for children is a universal problem

Over 60% of medicines were not studied in children.

Over 90% of them have not been studied in infants.
Status of pediatric medication and existing problems in China

“Three lacks”

- Lack of appropriate pediatric preparations
- Lack of pediatric medication information
- Lack of pediatric medication knowledge

• Few children-specific drugs available
• Inadequate dosage forms suitable for children
• Lack of strengths suitable for children
• Lack of pediatric medication information in drugs’ package insert
• Medication beyond the package insert is common
• Unreasonable drug selection
• Randomly change dosage form and dosing frequency of medication
• Unreasonable route of administration
• Incorrect method of administration
• Common repeated drug use
• A variety of drugs for combination therapy
Lack of drug varieties suitable for children

Drug registration information survey results as of May 31, 2015 have show:

- **2.27%** of drug registration information clearly specifies children
- **6%** of drug registration approval information announced by the SFDA clearly specifies young children or children
- **6.67% ~ 16.67%** of medicines are for children in *China's Essential Drugs List*
Lack of dosage forms suitable for children

2013 WHO Essential Medicines List for Children

- From the perspective of children’s safe drug use, marked tablets were included, conducive to sub-dosing for children
- From the perspective of facilitating pediatric use, chewable tablets, buccal tablets, powders, sprays, dry powders and transdermal patches were included to improve medication compliance

2012 Chinese Essential Drugs List

- Specific dosage form and strength of drugs were clearly specified for the first time, and importance was attached to coherence with the WHO Essential Medicines List for Children (EMLc).
- But it did not include marked tablets, chewable tablets, buccal tablets, sprays, transdermal patches and other dosage forms suitable for children.
Lack of strengths suitable for children

- Statistics have shown that Chinese children often use injections of strengths for adults, so that up to 60% of the prescriptions for children’s injections are wasted. 10% of the wasted prescription amount is far beyond half of the prescription’s total cost.
Lack of package suitable for children

- Children are curious in nature, and are likely to mock adults to open simply packaged drugs and may mistakenly swallow drugs to cause serious consequences. Therefore, strengthening child-resistant drug packaging is an important means to reduce mistaken swallowing of drugs by children and safeguarding children’s safety.

- More than 95% of drugs commercially available in China are not offered in child-resistant package, which increases the risks of pediatric medication. The awareness of the importance of child-resistant drug packaging is urgently to be improved.
Off-lable pediatric medication is very common

- The occurrence rate of off-lable pediatric medication:
  - 19.5%~26.0% in outpatients, and
  - 23.0% ~60.0% in inpatients

- 36%~92% of hospitalized children use drugs which have not be approved for pediatric use, and in neonates and ICU children is up to 80%~97% and 70%~92%
Insufficient study of drugs for children

- A variety of dosage forms of drugs are needed for children, and research and development is very difficult.
- Children have higher requirements for the safety of pharmaceutical agents.
- The market of children-specific drugs is small compared with the adult population, and thus the benefits are less compared with adult drugs, so pharmaceutical enterprises are not much enthusiastic about the development of children’s drugs.
Obstacles in the production and circulation of drugs for children

- The strengths and packages of drugs for children are usually smaller than for adults, and the price is relatively low.
- The strength of chemical drugs depends on the content of the API. The consumption of excipients of small-strength drugs for children is not less than large-strength drugs. In some preparations, the proportion of excipients in the production cost is even higher than the drug substance [1]. According to the Drug Differential Price Ratio Rules, small-strength drugs may suffer losses, so that manufacturers are unwilling to produce small-strength drugs for children.
- Shortage of pharmaceutical raw materials and drug supply will lead to the shortage of drugs for children.
- Tendering and networking, uniform drug price limitations and other policies also lead to the shortage of children-specific drugs in the hospital.
- Greatly restrain the production and circulation of small-strength drugs for children.
Lack of a national list of essential drugs and the policy for children

- The essential drug system is one of the most successful global health policies of WHO. The first WHO Essential Medicines List for Children was formulated in 2007.
- Essential drugs can meet the health care needs of the majority of the people. Essential drugs policy for children is an important initiative to promote the availability of drugs for children
- China started to working formulate a list of Essential Medicines List for Children in 2015.
Strategy

Chinese government is in action

Chinese Pediatrician are in action

- Chinese Pediatric Society
- Chinese Pediatrician Society
- Chinese Child Health Society
To solve the issues of pediatric medication, the Chinese government is making a lot of effort:

- **Good Clinical Practice for Drugs** included children as subjects of clinical trials.
- **Notice on strengthening the administration of maternal and child clinical medication**.
- **Chinese National Formulary (Chemicals and Biological Products for Children)**.
- **The National Essential Drugs List** expanded the varieties of drugs usable for children, as well as dosage forms and strengths suitable for children.

- **2003**: Chinese Children Development Outline (2011-2020) clearly proposed to “encourage the research, development and production of children-specific drugs.”
- **2011**: The National “Twelfth Five-year Plan for Drug Safety” proposed to “encourage the research and development of drugs for rare diseases and dosage forms suitable for children.”
- **2012**: Several Opinions for Ensuring Pediatric Medication Technical Guidelines for Pharmacokinetic Study in the Pediatric Population.
Ideas to promote China’s research and development of pediatric drugs

- Establish a mechanism and system to promote the research and development of pediatric drugs
- Improve the enthusiasm of enterprises
- Establish a responsibility chain
- Draft technical guidelines for the research and development
- Strengthen cooperation among researchers, enterprises and the government
- Strengthen international cooperation and exchanges
As of December 2013, the SFDA totally released 36 announcements, and the CFDA released 5 announcements. 63 of the 551 announced medical facilities had pediatric professions (totally 10 children’s hospitals, and maternal and child health hospitals). There were totally 155 pediatric professions. (2 pediatric hospitals to be announced)
## Recognition of qualified national drug clinical trial institutions—pediatric hospitals and professions

<table>
<thead>
<tr>
<th></th>
<th>Hospital Name</th>
<th>Specialties</th>
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<tbody>
<tr>
<td>1</td>
<td>Beijing Children’s Hospital, Capital Medical University</td>
<td>Pediatric endocrinology, pediatric nephrology, pediatric cardiology, pediatric respiratory,</td>
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<td></td>
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<td>pediatric traditional Chinese medicine, pediatric dermatology, pediatric chemotherapy,</td>
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<td>pediatric neurology, pediatric gastroenterology, pediatric infections, pediatric immunization,</td>
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<td>pediatric ENT, pediatric urology, pediatric general surgery, oncology, anesthesiology,</td>
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<td></td>
<td></td>
<td>medical imaging (diagnostic), emergency medicine (pediatric critical care medicine)</td>
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<td>2</td>
<td>Children’s Hospital of Chongqing Medical University</td>
<td>Pediatric respiratory, pediatric neurology, pediatric nephrology, pediatric immunization</td>
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<td>surgery</td>
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<td></td>
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<td>care, pediatric critical care medicine, pediatric anesthesia</td>
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<tr>
<td>6</td>
<td>Children’s Hospital of Shanxi ((Shanxi Maternal and Child Health Hospital)</td>
<td>Pediatric gastroenterology, pediatric respiratory, pediatric chemotherapy, pediatric neural</td>
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<td></td>
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<td>neurology, pediatric endocrinology</td>
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<td>gastroenterology</td>
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<td>respiratory, pediatric endocrinology, pediatric neurology</td>
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<td>Guangzhou Women and Children’s Medical Center</td>
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<td>cardiothoracic surgery, pediatric hematology, pediatric neurology</td>
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<td>10</td>
<td>Jiangxi Provincial Children’s Hospital</td>
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<tr>
<td>11</td>
<td>Shenzhen Children’s Hospital</td>
<td>Pediatric hematology, pediatric respiratory, pediatric neurology, pediatric traditional</td>
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<tr>
<td>12</td>
<td>Hunan Children’s Hospital</td>
<td>Child care, ENT, pediatric neurology, pediatric cardiology, pediatric hematology, pediatric</td>
</tr>
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Improve national strategies and policies and regulations to support clinical studies of pediatric drugs

● Establish a National Committee for Pediatric Clinical Trial Coordination
● Clarify the regulatory requirements for ethical management of pediatric clinical trials

Domestic units that have passed accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP): three hospitals

More than 62 hospitals throughout China have passed ethical certification by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) (excluding 2015)
Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)

- It is an international certification program developed by the World Health Organization (WHO) specifically for developing countries. The Forum Review Committees in Asia and the Western Pacific Region for Ethical REFCAP organizes implementation. With improving the capacity of ethics committees in ethical review as the tenet, the SIDCER aims to strengthen the protection of the rights and safety of human subjects in biomedical and social-behavioral studies.

- It is a certification to check whether the review qualification of independent ethics committees meets the review standards. The certification can promote the internationalization of hospital ethics committees, better protect the rights and interests of subjects, and elevate the overall level of clinical studies of the hospital. Ethics standards are an international language for clinical studies.

- More than 62 hospitals in China have passed the ethical certification by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER).
The Association for the Accreditation of Human Research Protection Programs (AAHRPP)

• AAHRPP is an independent international certification agency, aimed at protecting the welfare of subjects participating in medical studies, and promoting the scientificness and ethical norms of clinical studies by improving the ethical norms and professional operating levels of researchers and institutions through education and certification mechanisms.

• AAHRPP certification process is rigorous and based on the agency’s self-assessment, peer review and continuous education and improvement of the management mechanism.

• Not limited to the ethical norms and procedures, AAHRPP also pays attention to the regulation of scientific research management

• Domestic units that have passed the certification: three hospitals
It is the only national accreditation program that has been approved by the Certification and Accreditation Administration of China in the field of medical ethics, and also the world’s first traditional CM research ethics review system and accreditation program.

CAP accreditation is closely associated with FERCAP, AAHRPP and other similar international organizations, and supported by fund projects of the Asia-Pacific Economic Cooperation (APEC).

This year, the first batch of 7 hospitals passed the accreditation, including 2 general hospitals and 5 TCM general hospitals.
Construction of technical platforms for clinical evaluation study of new drugs for childhood leukemia

2011ZX09302–007–01

Project Leader: SHEN Kunling
Beijing Children's Hospital, Capital Medical University

Partners: Peking University First Hospital
Capital Medical University School of Pharmacy, etc.
Institute of Hematology & Blood Diseases Hospital
Chinese Academy of Medical Sciences
Children’s Hospital of Soochow University
Construction of technical platforms for clinical evaluation study of new drugs for childhood non-infectious diseases

2013zx09303003

Project Leader: Du Lizhong
Zhejiang Children's Hospital, Zhejiang University School of Medicine
According to the national GCP, introduce internationally advanced clinical trial management concepts and technologies, and establish a cross-regional, multi-center and nationally recognized technical platform for clinical evaluation study of new drugs for children up to international standards.
A clinical trial of phase III of EV71 vaccine (Sinovac) in Jiangsu Province, China

- **Conducted** by Jiangsu Provincial CDC, Sinovac Biotech, Chinese NIFDC, and Chinese NIVDC
- **Time:** 2012.1~2013.3
- **Aim:** To assess the efficacy, safety, immunogenicity and immune persistence of a vero cell based alum-adjuvanted inactivated EV71 vaccine (Sinovac) in infants and young children (aged 6-35M).
- **Methods:** Multicenter, stratified, randomized, double-blind, placebo-controlled clinical trial, in a 1:1 ratio to receive two intramuscular doses of either EV71 vaccine or placebo, 28 days apart. The surveillance period was 12 months. The primary end point was the occurrence of EV71-associated HMFD.

### Study Design and visiting schedule

- **Vaccine Group (5044 subjects)**: Vaccinated with Vero cell-based inactivated human EV71 vaccine with aluminum
- **Placebo Group (5033 subjects)**: Vaccinated with hydroxide diluents without EV71

A clinical trial of phase III of EV71 vaccine (produced by Institute of Medical Biology, Chinese Academy of Medical Sciences) in Guangxi Zhuang Autonomous Region, China

- Conducted by CDC of Guangxi Zhuang Autonomous Region CDC and Chinese NIFDC
- Time: 2012.2~2014.2
- Aim: To judge the effectiveness of a human diploid cell based alum-adjuvanted inactivated EV71 vaccine (Institute of Medical Biology CAMS) in healthy children 6 to 71 months of age.
- Methods: Multicenter, randomized, double-blind, placebo-controlled clinical trial, in a 1:1 ratio to receive two intramuscular doses of either EV71 vaccine or placebo, 28 days apart. The surveillance period was 11 months.

The primary end point was protection against HMFD caused by EV71.
Conclusion The EV71 vaccine consistently elicited immunogenicity and provided protection against mild-to-severe disease caused by EV71 for at least 1 year in infants and young children. A neutralizing antibody titer of 1:16 was associated with protection against EV71.

CONCLUSION THE INACTIVATED EV71 VACCINE ELICITED EV71-SPECIFIC IMMUNE RESPONSES AND PROTECTION AGAINST EV71-ASSOCIATED HFMD.
Summit Forum of “Make Medicines For Child-Children’s Drug Safety”


- Since 2008, cooperated with WHO, the Submit Forum has been held for six consecutive years

- Discuss problems and solutions for better medicine for children

Seminars, research, exchanges
Relevant initiatives of China to solve pediatric medication issues

In August 2011, the Ministry of Health released *Notice on strengthening the administration of maternal and child clinical medication* (W. B. Y. Z. F. [2011] No. 112), and organized the formulation of *Chinese National Formulary (for Children)* which was published in January 2013.

Publishing first *Chinese National Formulary for Children*
Opinions for Ensuring Pediatric Medication by Chinese Government in 2014

一、加快申报审评，促进研发创制
（一）建立申报审评专门通道。针对国内已上市使用但国内缺乏且临床急需的儿童适宜品种、剂型、规格，加快审评审评进度。
（二）建立鼓励研发创新机制。根据我国儿童疾病防治需求，借鉴国际经验，逐步建立鼓励研发的儿童药品目录，并将其纳入国家“重大新药创制”科技重大专项、蛋白类生物药和疫苗重大创新发展工程，整合优势单位协同创新研发，提升产业自主创新能力，引导和鼓励企业优先研发生产。
（三）鼓励开展儿童用药临床试验。加强儿童用药临床试验管理、推动临床试验平台建设和研究团队能力建设，提高受试者参与度。探索建立新药申报时提供相关儿童临床试验数据及用药信息的制度。对已上市品种，要求药品生产企业及时补充完善儿童临床试验数据。

二、加强政策扶持，保障生产供应
（一）对儿童用药价格给予政策扶持，儿童专用剂型可单列代表品，不受成人药品定价水平影响；对儿童适宜剂型，研究规定较为宽松的剂型比价系数。对部分临床必需但尚在专利保护期内的进口儿童用药，探索建立价格谈判机制、推动降低药品价格，满足临床需求。发挥医疗保险对儿童用药的保障功能，按规定及时将儿童适宜剂型、规格纳入基本医疗保险支付范围。
（二）优先支持儿童用药生产企业开展产品升级、生产
Established **National Pediatric Medication Expert Committee**
in 2015

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**国家卫生计生委药物政策与基本药物制度司**

国家卫生计生委办公厅关于成立国家卫生计生委儿童用药专家委员会的通知

卫办药政函〔2015〕150号

各省、自治区、直辖市卫生计生委，新疆生产建设兵团卫生局：

为进一步落实国家卫生计生委等6部门《关于保障儿童用药的若干意见》（卫药政发〔2014〕29号），充分发挥儿科专业学会的学术优势，完善儿童用药数据，促进儿童用药安全科学合理使用，保障儿童基本用药需求，决定组建国家卫生计生委儿童用药专家委员会。

国家卫生计生委儿童用药专家委员会的主要职责为：负责组织相关专家总结儿科临床用药经验及安全用药数据，形成行业共识，推动建立科学规范的儿童用药指南，对部分已临床使用多年的药品说明书中缺乏儿童用药数据的药品进行组织论证，补充完善儿童用药数据，对保障儿童用药工作提出建议，开展相关具体指导实施工作。

委员会办公室设在首都医科大学附属北京儿童医院，负责日常管理工作。

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郝建宁 北京中医药大学中药药理系主任、教授
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杜守颖 北京中医药大学制药系主任、教授
杜军保 北京大学第一医院儿科副主任、主任医师
李廷玉 重庆医科大学附属儿童医院院长、主任医师
李培红 中国中医科学院西苑医院药剂科主任、主任药师
李彩凤 首都医科大学附属北京儿童医院风湿免疫科主任、主任医师
1. Thoroughly investigate the status of pediatric medication (compare with the survey data in 2011);

2. Propose a candidate list of national essential drugs for children (suggested version);

3. Propose a list of national medical insurance-covered drugs for children (suggested version);
4. Pediatric medication guidelines

- Organize experts to summarize clinical medication experience and medication safety data, and form industry consensus.
- Promote the establishment of scientific and standard pediatric medication guidelines.
- Guide enterprises over research, development and application, and direct enterprises to organize production
5. Supplement and improve the package insert of children’s drugs

- Organize demonstration, and supplement and improve pediatric medication data for some drugs that have been clinically used for many years but the package insert lacks pediatric medication data.

- Combined with clinical practice, recommend pilot drugs whose package insert to be preferably modified, and guide enterprises to modify the package insert of drugs.
6. Investigate children’s drugs in short supply

- Collect and summarize urgently needed drugs in pediatric clinical practice (including varieties, dosage forms and strengths suitable for children), and recommend drugs to be included the list of children’s drugs encouraged for research and development.
- Guide and promote the research and development, registration and production of urgently needed drugs.
7. Carry out comprehensive evaluation of children’s drugs

- Screen children’s hospitals with comprehensive advantages and TCM hospitals with high pediatric TCM diagnosis and treatment levels nationwide, and establish and improve a comprehensive evaluation system for children’s drugs.
- With essential drugs as the key, establish clinical databases on children’s medication.
- Collate and summarize the usage and dosage of children’s medication, efficacy, pharmacokinetics and combination interaction data in all localities, and regularly carry out comprehensive evaluation.
8. Promote the pediatric training in better medicine for children;

- Improve the contents of pediatric education and training, and develop special training plans.
- Focus on strengthening pediatric training in grassroots medical staff (organize tour lectures on essential drugs and children’s prescriptions), improve their professional levels and service capabilities, and standardize pediatric medical behaviors.
9. Strengthen the publicity of reasonable medication, and improve the whole population’s health awareness

- Popularize medical science and safe medication knowledge, guide the public to form good medication concepts and habits, maximally ensure the medication safety of children, and safeguard children’s rights and benefits.
- Work together with relevant associations and foundations to establish a “micro” platform for popularization of science.
10. Carry out drug clinical trials in children

- Promote the construction of clinical trial platforms and research team’s capacity building, and improve the participation of subjects
- Explore and establish a system for providing relevant clinical trial data in children and medication information for the application of new drugs;
- For marketed varieties, the drug manufacturers are required to timely supplement clinical trial data in children
11. Carry out research on precision medicine

- Carry out genomics research for children’s drugs
- Guide individualized precision medical care for children’s drugs
- Clinical use of drug genetic testing
- Select doses according to gene polymorphism, and achieve individualized medication
12. Regulate the application of traditional Chinese medicines in children

- Give full play to the characteristic advantages of Chinese medicines in children, summary the clinical medication experience of TCM pediatrics, and strengthen the research and development of pediatric Chinese patent drugs and in-hospital preparations.

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- Improve clinical assessment criteria, and promote the re-research on, re-evaluation of and relevant technical standards for the safety, efficacy and economy of pediatric Chinese medicines.

- Regulate the functions, usage, dosage, combinations and warnings of adverse reactions pediatric Chinese medicinal products, and standardize the application of Chinese medicines in children.
13. Popularize the concept of children’s pharmacovigilance and knowledge

- Pharmacovigilance: A science and activity to discover, assess, understand and prevent adverse drug reactions (ADR) or any other drug-related problems. --WHO The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products

- In view of the above-mentioned characteristics of children, the lack of pediatric medicines, medication beyond package insert, late start and difficulties of drug clinical trials and other characteristics

- Pharmacovigilance is even more important in the application and practice of pediatrics

- The concept of pharmacovigilance was introduced to China very late, and even later in pediatrics
14. Pay attention to drug hypersensitivity and drug allergy

- **Drug hypersensitivity (DHR):** Adverse drug reactions similar to allergies caused by drugs (active ingredients and excipients), under normal circumstances and in the presence of suspected drug allergy, are preferably referred to as DHR, because it is difficult to distinguish drug allergy and non-allergic DHR merely based on the clinical manifestations.

- **Drug allergy:** When caused by the immune system, such adverse reactions are referred to as drug allergy.
15. International cooperation with AAP, NIH, FDA, EMA, PhRMA, BIO, Academia, Patient Advocates and Industry

AAP sponsored meeting that issue a resolution for the creation of a Pediatric Clinical Trial Network – November 2014
We, the Chinese Pediatrician would like to unite with all of you throughout the world to striving for the health of children.

If the children is wise, the country is wise.

If the youth is rich, the country is rich;

If the children is strong, the country is strong;

If the youth is independent, the country is independent;

If the youth is free, the country is free;

If the youth progresses, the country progresses;

If the youth is powerful around the globe, the country is powerful around the globe.

*The Young China by Liang Qichao*