Development of ADR Reporting and Monitoring in China

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Since the 20th century, Drugs play an important role in human disease prevention and treatment, as well as protection of health.

In China, along with the development of medicines and the health-care system, rational drug use and drug safety are becoming increasingly important concerns.

Drug safety not only relates to public health, but also affects social stability and economic development to some extent.

At the same time, monitoring the effects of drugs after they’ve been released poses a major challenge.
1. Development of adverse drug reactions (ADR) monitoring in China

"Thalidomide" which led to more than 10,000 infants seal limb deformities shocked the world.

It was only following the Thalidomide scandal that every country began to set up ADR reporting and monitoring systems.
1. Development of adverse drug reactions (ADR) monitoring in China

△ In the early 80s, the Chinese government started to carry out pilot projects to monitor ADR.

△ In 1989, the Ministry of Health ADR Monitoring Center was established.

△ In March 1998, it formally joined the WHO International Drug Monitoring Program.
1. Development of adverse drug reactions (ADR) monitoring in China

- The National ADR Monitoring Centre was founded in 1998.

- ADR monitoring was strengthened in terms of:
  - legal framework,
  - monitoring systems,
  - information technology application,
  - administrative control,
  - capital investment
  - other aspects.
(A) Gradual improvement of laws and regulations

- 《Drug Administration Law of the People's Republic of China》: “The State applies a reporting system on adverse drug reactions”

- 《Management Measures of Adverse Drug Reactions Reporting and Monitoring》

  responsibilities and duties of government authorities, drug manufacturers, distributors and medical facilities. procedures and requirements of ADR reporting, evaluation and management.
(B) Initial establishment of ADR monitoring organizational system

- By the end of 2002, provincial ADR Monitoring Centers had been set up in 31 provinces.

- By the end of 2010, China will complete the organization of ADR monitoring systems in all city-regions (about 400 centers in total), thereby establishing a nationwide surveillance system.
Since 1998, the number of ADR reports has increased dramatically.
The quality of the ADR reports is gradually becoming more standardized and the utilization rate of reports is rising every year.

China has established a National ADR Monitoring Information Network System as well as completed an online reporting network.
(C) ADR reporting and monitoring

- Since 2001, 《Adverse Drug Reactions Newsletter》
  30 times, informing people of nearly 50 drugs with serious safety problems

- Based on ADR monitoring and evaluation, prompt measures have been taken against drugs with serious ADR occurrence or potential drug safety problems:
  - modification of the package inserts
  - conversion of OTCs to prescription drugs
  - suspension of sales and use of some drug

- All of these measures have been fairly effective at reducing the risk of using drugs.
2. Challenges of ADR reporting and monitoring in China

- Firstly, the present ADR monitoring system in China depends on the “spontaneous reporting system”.
  - high underreporting rate,
  - failure to calculate the incidence rate,
  - uncertain causality judgment
  .......

- Secondly, quality of some ADR reports can not meet the requirements of analysis and evaluation.
  - lack a clear description
  - data standardization is low
  - the contents of reports mostly focus on known and common
2. Challenges of ADR reporting and monitoring in China

- In other words, the China ADR Monitoring Information Network has achieved ADR reporting capabilities, but failed to fully accomplish an automatic warning and assessment system.

- There is still a lot of work to do in the research and exploration of improved ADR monitoring.
3. Continuous intensification of ADR monitoring

- In recent years, China’s ADR monitoring has gradually developed towards pharmacovigilance and expanded the scope of monitoring.
3. Continuous intensification of ADR monitoring

- Currently, we are revising the requirements and procedures of ADR reporting, and intend to intensify the verification, investigation, and evaluation of case reports.
- We have proposed to implement the intensive monitoring system.
- We are constantly improving the software and hardware that make up the ADR Monitoring Information Network.
- We also continue to strengthen exchange and communication with WHO and other countries in terms of drug safety information.
Summary

- Drug safety and rational use are very important.
- The practice of ADR monitoring in China has made great progress.
- We still face challenges.
- We will keep on intensifying drug safety monitoring and risk management.
Thank You All for Your Attention