BACKGROUND
• ADR monitoring in China, despite a late start, has been rapidly developed with a new monitoring system established since 2002.
• Problems with China’s ADR monitoring system have been reported, such as poor quality of reports, narrow coverage of monitoring network, and lack of risk warning and controlling measures.1
• The scientific evaluation mechanism for China’s ADR monitoring and reporting system remains to be set up.
• China’s “Drug Administration Law” is currently under revision. Much attention will be paid to promoting risk management and improving safety of medication use.

OBJECTIVES
• The aims of this study were to: (1) provide an overview on China’s ADR monitoring system; (2) evaluate the implementation effects of China’s ADR monitoring work; and (3) provide insights for improving China’s ADR monitoring system.

METHODS
• Literature and policy review were conducted to evaluate China’s ADR monitoring system with regard to regulations, organization and operation mechanisms.
• ADR data (1998-2013) were collected from the National ADR monitoring centers as well as the on-site data collection from the National Center for ADR Monitoring.
• Effect assessment was made on the basis of conceptual framework of process, output and outcomes.2 Framework were used to measure:
  • Process—processes of change, such as ADR regulations, organization and technical equipment.
  • Output—the result of processes, such as information processing and risk control actions.
  • Outcome—the ultimate outcomes of an action, such as number of ADR reports and ratio of sources.

RESULTS
• Process
  • China’s ADR monitoring regulations include 3 parts—laws, regulations and rules (Figure 1).
  • China’s ADR monitoring work is organized by the food and drug administration department (CFDA) and health department (NHFPC). A total of 34 provincial and 333 municipal ADR monitoring centers were established by 2012 (Figure 2).
  • The number of China’s ADR monitoring network users increased from 33,878 to 150,000 during 2009 to 2013.

• Output
  • National ADR monitoring center has published 40 issues of "ADR Information Bulletin", and 65 issues of "Pharmacovigilance News" since 2009 (Table 1).
  • During 2009-2013, risk controlling measures of sales restriction and suspension were taken 6 times, together with 49 drug label modifications and 8 revocations of the approval number (Table 2).

• Outcome
  • During 1998 to 2013, the number of ADR reports increased from 519 to 1,317,000 (Figure 3). The overall number of ADR reports per million population reached 968 by 2013 (Figure 4).
  • New and serious ADR reports accounted for 13.3% to 22.10% during 2008 to 2013 (Figure 5).
  • While the majority of reports were submitted by medical institutions (74.8% to 84.6%), the reports from manufacturers and sellers increased from 12.30% to 24.4% (Figure 6).

DISCUSSION AND CONCLUSION
• China’s ADR monitoring system has achieved rapid progress in recent years and functioned well to some extent.
• The potential problems are the structural imbalance of ADR report sources and lack of sufficiency and diversification in risk control actions. Efforts are needed to remove the barriers in ADR monitoring work.
• Evaluation of ADR monitoring and reporting system was merely based on the available information and data, and thus the results may not represent the extent of all evidence evolved and accumulated in recent years.
• Cost-effectiveness could be considered as an important indicator for evaluating ADR monitoring system; however, costs were not studied yet.

REFERENCES