AS1-5

Advance in antidotes management

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Rationale: Antidote therapy is a major element for treating poisoned patients. However, many of them are orphan drugs. Shortage of antidotes compromises the effectiveness to treat the patients though diagnosis is made and line of management is known. The shortage is worldwide, but getting more serious in developing countries. A new system is designed and operates recently in Thailand.

Method: This is a collaborative work among various agencies. A system includes selection and procurement of essential antidotes; distribution and stock specific antidotes according to their urgency and availability; logistics and communication; web-based administration including searching by geographic information system and real-time online stock; education and training of health personnel; and monitoring and evaluation of the system.

Result: In the first year, 176,600 USD were allocated for this program. Six antidotes (sodium nitrite, sodium thiosulfate, methylene blue, dimercaprol, succimer and glucagon) were selected and procured. Cyanide antidotes and methylene blue were distributed and stocked in all general hospitals. Dimercaprol was in tertiary care centers and glucagon in only a poison center. Succimer was in government pharmaceutical organization. More than 800 health personnel participated in the training workshops held nation-wide. During the first year, 57 patients had derived benefit from the program including poisoning from cyanide, methemoglobinemia, hydrogen sulfide, copper and lead.

Summary: A system is able to save hospitals’ expense for stocking the drugs and secures the country from poisoning problems. It is flexible for rectifying other orphan drugs and potentially sufficient to share with neighboring countries.

AS1-6

How should we make the most of the toxicological data in the clinical fields?

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Toxicological data is an important reference to estimate the safety in the early phase of clinical trials. Especially, in the First in Human trials, the role of toxicological data is more crucial and principal investigator has to presume which point should be paid more attention according to the data. On the other hand, in the later phase of trials, it is not so frequent to be paid attentions to the non-clinical data, unless some severe adverse event occurred, which gives us opportunity to look back to it.

In my talk, I would like to examine the possibility to make the most of non-clinical (toxicological) data not only in the early phase of clinical trials, but also later phase or post-marketing stage by comparing safety data between non-clinical and clinical (trial and post-marketing stage) of some drugs. Moreover, I would like to consider the necessity of new biomarker as a more accurate indicator which will link non-clinical data and clinical safety assessment.