EXTRAPOLATION OF EXPERIMENTAL ANIMAL DATA TO HUMANS

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For new chemical compounds being introduced, or planned to be introduced into practical use, animal studies provide basic information on their toxicity, including toxic doses and concentrations, types of injury and mechanism of toxic action. Studies with laboratory animals also provide data which may be utilized to estimate human risk and to establish new or correct existing environmental exposure limits for humans. The practical use of animal toxicity studies is based on the fundamental assumption that the results make the prediction of the toxic effects of chemicals in humans possible. This assumption is based on the similarities in the anatomy and physiology of mammalian species. For most substances, the pathogenesis of poisoning is the same in humans and other mammals; therefore, the signs of intoxication are also analogous. Qualitative effects of the toxic action of chemicals in humans can usually be inferred from animal studies with a high degree of certainty. On the other hand, the accuracy and reliability of a quantitative prediction of toxicity in humans depend on a number of conditions - choice of animal species, design of the experiment and methods of extrapolation.

Species Differences

Qualitative differences in the sensitivity of humans and other animals are exceptional. No poison with a selective action on humans alone has yet been found. However, the problem exists that some effects are difficult to measure in experimental animals: for example, intelligence and the more esoteric behavioural changes. Social factors, so important to humans, cannot be evaluated in experimental animals.

The most difficult problem in the extrapolation of animal data to humans is the presence of quantitative differences in toxic responses between humans and other animals and among various animal species. As far as lethal doses are concerned, man is considered to be rather more sensitive than certain laboratory animals to lethal doses, but many