EFFECT OF DRUGS UPON THE FETUS AND THE INFANT

It is a basic premise of pediatrics that physical size is not the most important difference between children and adults. There is increasing awareness that it is also necessary to make more than a quantitative distinction between infants and children. The fetus and the newborn infant often behave so differently as to warrant consideration as separate categories of the human species. This necessitates re-evaluation of the effects of drugs independently in each category of the human so that they may be used safely.

Existing drugs and agents that are developed in the future for use in the fetus and in infants must be subjected to more extensive preclinical investigation than is being carried out at the present time. The pharmacologic responses of the immature human may differ greatly both quantitatively and qualitatively from those of the adult. As a result, data obtained from tests in mature animals and human adults or older children cannot be accepted as a satisfactory basis for recommendations concerning the fetus and infant.

The pharmacologic properties of drugs should be studied in vitro and in vivo in the fetus and newborn animal and compared with those in the adult of the same animal species. Of particular importance would be a knowledge of the LD₅₀, dose response, metabolism, and distribution and disposition of the drug. These determinations should be performed in two or more animal species (a rodent and non-rodent species). Pharmacodynamic actions and clinical effects of drugs in humans should be assessed in clinical situations in which they may be useful.

In order to pursue these principles, it is recommended that drug labels should specifically indicate the extent of existing information concerning the use of the agent in the fetus and the infant. When there have been no pharmacologic studies of a drug in immature subjects, an explicit statement of this fact should be indicated on the drug label or in a readily available package leaflet. Physicians who administer drugs to the fetus and the infant must be alert to unusual effects in this subdivision of the human species.

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