

Vitamin K Prophylaxis

excerpts from a paper by Karin Rothville DipCBEd, New Zealand

Why is my baby injected with Vitamin K at birth?

Haemorrhagic Disease of the Newborn (HDN) is a bleeding disorder associated with low levels of vitamin K in newborn babies. It was first defined in 1894 by Townsend as spontaneous external or internal bleeding occurring in newborn infants not due to trauma, accident or inherited bleeding disorders such as haemophilia. Previously, there were no generally agreed upon criteria to determine causes of haemorrhaging, so any diagnosis was based solely on the opinion of the attendant medical personnel.

Infants are born with low levels of vitamin K compared to adults and this is termed 'vitamin K deficiency'. Up to 50% of babies develop this 'vitamin K deficiency', but bleeding occurs in only a fraction of these cases. In most it starts after birth, becomes progressively more severe over 48-60 hours, then spontaneously corrects itself by 72-120 hours.

HDN has always been rare—in Britain, where maternity units practised a selective policy of vitamin K administration, the incidence was no more than 1 in 20,000 in the years 1972-80. Estimates for late onset HDN are 4-8 per 100,000. Incidence also seems to vary from country to country. Birkbeck reports that HDN is almost unknown in central Africa.

What are the risks of Vitamin K injection?

Konakion ampoules contain phenol, propylene glycol and polyethoxylated castor oil as a non-ionic surfactant. Studies in animals given polyethoxylated castor oil have shown a severe anaphylactic reaction associated with histamine release. Strong circumstantial evidence implicates polyethoxylated castor oil in similar reactions in humans. Polyethoxylated castor oil, when given to patients over a period of several days, can also produce abnormal lipoprotein electrophoretic patterns, alterations in blood viscosity and erythrocyte aggregation (red blood cell clumping). Individuals sensitive to this base are contraindicated from using Konakion. New Ethicals Compendium also warns that the use of Konakion can cause jaundice and kernicterus in infants. Other listed side effects include flushing, sweating, cyanosis, a sense of chest constriction, and peripheral vascular collapse. Local cutaneous and subcutaneous changes may occur in areas of repeated intramuscular injections.

This synthetic, injectable vitamin K formulation was never subjected to a randomised, controlled trial. In new drugs that are to be used for prophylaxis, the usual risk/benefit analysis does not apply, since the individual is not ill. The ethical principle of non-maleficence (*primum non nocere* – first do no harm) applies and the trials must thus be larger in order to identify any previously unrecognised side effects. Since this did not happen, nor was there any long term follow up, we actually have little idea of the effects of this drug on newborn babies.

The risks of injecting vitamin K into a newborn baby are nerve or muscle damage as the preparation must be injected deeply into the muscle, not subcutaneously under the skin. There is also the documented risk of injecting the baby with the syntocinon intended for the mother. As stated in the product information, infants can suffer from jaundice or kernicterus (brain damage from a build-up of bile pigments in the brain) from Konakion. Infants who have the enzyme deficiency G6PD (glucose 6 phosphate dehydrogenase) are at particular risk from vitamin K. The other risk factor is the possible increased chance of childhood cancer, especially leukemia. The link between intramuscular vitamin K and childhood cancer has not been definitively proved, nor has it been completely disproved.

Plasma vitamin K levels in newborns reach 300 times normal adult levels for oral and almost 9000 times adult levels for injected vitamin K. No research has been done on the effect of such high levels. Physiological levels of vitamin K maintain a careful balance between coagulation and anti-coagulation, and we have no idea what the effects of upsetting that delicate balance may be.

What To Do About Vitamin K Injections in New York

by Gary Krasner, Director, Coalition for Informed Choice

Vitamin K administration is mandated by New York State law. A hospital is not obligated to provide an oral administration of the vitamin. You need a physician, nurse or physician assistant to write a prescription for the oral vitamin K. A nurse can administer the order once the baby is born. After you take the baby home, you need your practitioner to write orders for subsequent vitamin K doses and administer them.