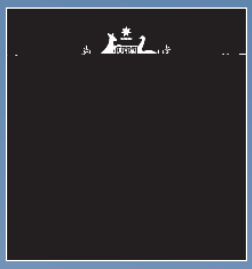

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NHMRC Council advised the CEO of NHMRC to re-issue this publication at the 183rd Session of Council, 8 October 2010.

Recommendations

1. **All newborn infants should receive vitamin K prophylaxis.[8,17]**
2. **Healthy newborn infants should receive vitamin K either:**
   - **by intramuscular injection of 1 mg (0.1 mL) of Konakion® MM[1] at birth. This is the preferred route for reliability of administration and level of compliance.**

     or
   - **as three 2 mg (0.2 mL) oral doses of Konakion® MM, given at birth, at the time of newborn screening (usually at three to five days of age) and in the fourth week. The last dose is not required in infants predominantly formula fed. It is imperative that the third dose is given no later than four weeks after birth as the effect of earlier doses decreases after this time. Undertaking this form of prophylaxis requires that the parent accepts responsibility and that clinicians support and advise them in the administration of the third dose. If the infant vomits or regurgitates the formulation within one hour of administration, the oral dose should be repeated.[1] If at the time any oral dose is to be given the infant is sick, vomiting or unable to take it by mouth, then medical advice should be sought as to whether the intramuscular preparation should be given.**
3. **Newborns who are too unwell and are unable to take oral vitamin K (or whose mothers have taken medications that interfere with vitamin K metabolism) should be given 1 mg of Konakion® MM by intramuscular injection at birth. A smaller intramuscular dose of 0.5 mg (0.05 mL) should be given to infants with a birth weight of less than 1.5 kg.**
4. **Parents should receive written information during the antenatal period about the importance of vitamin K prophylaxis, and the options and relevance of oral or intramuscular prophylaxis. Health practitioners and institutions should ensure that appropriate informed consent procedures are in place and are followed.**
5. **A mechanism should be in place to ensure that the decision made antenatally about the method of prophylaxis is still valid and is communicated to staff caring for the mother during childbirth and postnatally.**

1 The Konakion® MM Paediatric Product Information reflects the Joint Statement and Recommendations.

6. **Hospitals should have written protocols for medical and nursing staff to administer prophylactic vitamin K to infants. These should include that it be routine practice to record the date, dose and method of administration in the infant's personal health record.**
7. **Child health workers and parents should be aware that unexplained bleeding or bruising in infants is uncommon and should be promptly investigated and treated. Information on unexplained bleeding should be included in the general information given to parents antenatally.**
8. **Further research should be undertaken into the implementation strategies for oral Konakion® MM and for the efficacy of Konakion® MM by any route. The possibility of prophylaxis via maternal supplementation to enhance levels of vitamin K in breast milk should also be investigated. However it is generally believed that a baby cannot receive treatment via breast milk.**
9. **The Australian Paediatric Surveillance Unit should be supported to continue monitoring the incidence of Vitamin K Deficiency Bleeding.**

Introduction

K prophylaxis to newborns, as well as on the new Konakion® MM Paediatric formulation, and as such the recommendations in the Joint Statement remain current.

This revised Joint Statement has been widely consulted, including receiving advice from clinicians, government health departments, professional colleges and the Council of NHMRC in 2010.

Background

The term 'haemorrhagic disease of the newborn' was first used in 1894 (Townsend 1894) to describe bleeding in the newborn, which was not due to traumatic birth or to haemophilia. Later many cases were found to be associated with vitamin K deficiency. The term 'vitamin K deficiency bleeding' (VKDB) has now been adopted (Sutor et al 1999). This is preferred since not all bleeding in the newborn is due to vitamin K deficiency and bleeding due to this cause is not confined to the newborn.

Vitamin K occurs in two forms, vitamin K1 whose source is dietary intake and vitamins K2 (menaquinones) that are produced by gut bacteria. All newborn infants have a relative vitamin K deficiency at birth (Shearer 1992). Vitamin K1 crosses the placentaei(ns,)he neessiotollentsmafinedaei(ns,)ns in the ne)5[o tmin K d(whichvitaa 30:1

Diagnosis

VKDB includes spontaneous or excessive induced bleeding (eg venipuncture or surgery) at any site associated with decreased activity of the vitamin K dependent coagulation factors (II, VII, IX and X) with normal activity of vitamin K independent factors fibrinogen levels and platelet count (Sutor et al 1999). Confirmation of the diagnosis requires that the coagulation disorder is rapidly reversed following vitamin K administration and that other causes of coagulopathy are excluded.

Classification

Prophylaxis

In Australia prophylaxis with a single IM injection of 1 mg Konakion® (cremophor) was introduced in the early 1970s. This was initially given to 'sick' infants such as those born preterm or following perinatal asphyxia, and later became routine for all infants.

In 2000 over 95 per cent of approximately 260,000 newborn infants born in Australia each year received IM vitamin K® (cremophor) prophylaxis at birth, most of the remainder receive either oral prophylaxis with repeated doses of the same formulation and a small number receive no prophylaxis (Australian Paediatric Surveillance Unit – unpublished). In 1994 the NHMRC recommended that all infants should receive prophylaxis and that the IM route was preferred for reliability of administration. Prophylaxis has been recently reviewed (Brousson et al 1996, Cornelissen et al 1997, Sutor et al 1999, Von Kries 1999) and these studies underpin the statements below.

Cremophor formulation is no longer in use. When the Joint Statement was first released in 2000 Konakion® MM Paediatric had just been introduced. Konakion® MM Paediatric is now the current formulation of vitamin K prophylaxis.

Appendix: History of the development of the Joint Statement

In 2000, the National Health and Medical Research Council (NHMRC) was requested to:

- **review research published since 1994 on the efficacy, safety and bioavailablity of the new vitamin K formulation, Konakion® MM Paediatric when given orally or intramuscularly**
- **consider the different needs of formula and breast fed infants for the administration of vitamin K**
- **consider if a requirement for booster doses of vitamin K will have implications for the NHMRC Australian Standard Vaccination Schedule,**
- **prepare advice for health care workers and parents on the need and schedule for vitamin K administration**
- **recommend areas for further research.**

A multidisciplinary Working Party was formed to address these issues.

Methods

The Working Party had two face to face meetings and two teleconferences. The detailed submission to ADEC by Roche Australia for the licensing of Konakion® MM Paediatric was made available. In addition a systematic literature search was undertaken of MEDLINE (1994-2000) and the Cochrane Library for reports on the incidence of vitamin K deficiency bleeding and effectiveness of different forms of prophylaxis. This was supplemented by a search for unpublished, ongoing orplanned studies through contact with Roche Australia and international experts in the field. The experts included Drs Shearer, Tripp, McNinch and Hey in the UK, Sutor and Von Kries in Germany and Greer in the USA.

A five week phase of full public consultation was undertaken following NHMRC endorsement of the draft Joint Statement and Recommendations.

The final product was endorsed by Council in October 2000. In 2006, NHMRC Council recommended the Joint Statement be reissued unchanged.