



OPERATIONAL GUIDELINES

Injection Vitamin K Prophylaxis at Birth (in facilities)



Child Health Division

Ministry of Health and Family Welfare

Government of India



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Preface

Vitamin K Deficiency Bleeding (VKDB) is of particular concern in neonates as they are born with low levels of vitamin K and the risk increases further in those who do not receive vitamin K prophylaxis at birth. Affected babies tend to have prolonged and excessive bleeding and in the serious cases, bleeding may occur in the brain which may be life threatening or may lead to long term morbidity.

Vitamin K Prophylaxis at birth has sufficient evidence with respect to effectiveness and the safety in preventing VKDB. The cost for preventing one case is considerably smaller than those of treating the affected infant and looking after survivors with lifelong disabilities. Intramuscular Vitamin K prophylaxis at birth is routinely used in well-resourced settings. With a significant increase in institutional deliveries in public health facilities in recent years, the need for implementing Vitamin K prophylaxis for all newborns delivered at health facilities has come to the fore.

In view of this, Government of India has taken a decision to use Injection Vitamin K for all facility births at all levels including sub centres. The communication regarding the same has already been disseminated to the states. I hope, this guideline regarding the operational issues and the key messages for the service providers will help the programme managers a great deal in implementing this initiative with full vigor.


4/4/2014
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Acknowledgement

The Government of India has given the 'call to action' on achieving the goals of reducing maternal, infant and neonatal mortality through the implementation of Reproductive, Maternal, Neonatal, Child and Adolescent health (RMNCH+A) strategy. Keeping these goals in view, facility based newborn care gains great significance. Quality of care at these facilities for newborns will play a key role in the RMNCH+A strategy.

The Ministry of Health & Family Welfare, Govt. of India has taken a policy decision to administer Prophylactic Vitamin K Inj. to all new borns delivered at public health facilities to prevent VKDB. The Operational Guidelines for Inj. Vit.K Prophylaxis at birth has been developed by hard work of many individuals and institutions.

Dr. P.K. Prabhakar, Deputy Commissioner, MOHFW coordinated the development of these guidelines and led the Team of CH Division and Experts from various Institutions and Development Partners.

I sincerely acknowledge the contributions of all the experts and contributors.


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Acronyms

VKDB	Vitamin K Deficiency Bleeding
HDN	Haemorrhagic Disease of Newborn
EDL	Essential Drug List
SNCU	Special Newborn Care Unit
NBSU	Newborn Stabilization Unit
SBA	Skilled Birth Attendant

Introduction



Vitamin K Deficiency Bleeding (VKDB) previously known as Hemorrhagic Disease of the Newborn (HDN), is a well-known clinical entity for over 100 years. Vitamin K is required for the synthesis of coagulation factors that prevent and control bleeding. All neonates have low levels of Vitamin K owing to poor transport of Vitamin K across placenta, low Vitamin K content in breast milk, and because gut colonization that is critical for its synthesis takes a few days to establish.

Clinical Forms of VKDB in Newborns

There are three forms of VKDB:

- a. **Early VKDB** presents with bleeding within 24 hours and occurs in newborns of mothers taking drugs such as anticoagulants, anticonvulsants (phenytoin, phenobarbitone) or anti-tubercular drugs (Rifampicin). This condition can be prevented by administering Vitamin K to the mother receiving such drugs at least 24 hours before delivery, and/or replacing the offending drugs. Neonatal Vitamin K prophylaxis does not prevent this form of bleeding disorder.
- b. **Classical VKDB** is the commonest variant and presents after 24 hours but within the first week of life. Incidence of classical VKDB varies from 0.01 to 1.5% depending upon the feeding pattern and Vitamin K prophylaxis status. Bleeding sites include the umbilical stump and GI tract, or the surgical wound

(e.g. following circumcision). Intracranial hemorrhage (ICH) is rare. The incidence is higher in breastfed babies than in those who are formula-fed. Neonatal Vitamin K prophylaxis is effective in preventing classical VKDB.

- c. **Late VKDB** is uncommon. The median incidence of late VKDB in infants who have not received any prophylaxis at birth is 30 per 100,000 births (range: 4.4 to 80). Less developed countries have almost 10-fold higher incidence than developed nations (median: 80 vs. 7.2 per 100,000 births) with an incidence of 4.2 to 7.4 per 100,000 births. It manifests between 2-12 weeks of age primarily among breastfed infants who have received no or inadequate Vitamin K prophylaxis. In addition, infants on antibiotics and those having intestinal malabsorption are at risk of this disorder. Intracranial hemorrhage is very common in this disorder and may be life threatening. Other sites of bleeding are skin, mucus membranes, and GI tract. Parenteral neonatal Vitamin K prevents late VKDB except in those with severe malabsorption syndromes.

Although, reliable estimates of VKDB from our country are not available, there is agreement among experts that the above description of the disease is applicable to our setting as well and measures should be taken for prevention.

Role of Vitamin K Prophylaxis in Preventing VKDB

A Cochrane review of 2000-2003 supports the use of Vitamin K for all newborns. Vitamin K administration to infants soon after birth is an effective, safe, and sustainable approach to preventing VKDB and is possible to upscale it. The risk of a baby developing VKDB can be reduced to 1/1 million by the administration of Vitamin K after birth.

Studies have shown a 27% relative risk reduction for classical Vitamin K deficiency bleeding with intramuscularly (IM) Vitamin K. The preferred method of Vitamin K prophylaxis is by intramuscular route. Oral Vitamin K prophylaxis requires repeat doses, hence not preferred. Intramuscular Vitamin K prophylaxis is a routine in neonatal practice in developed countries as well as in most tertiary care centres in our country.

VKDB is a significant threat to neonates. However, it can be prevented almost entirely by Vitamin K administration soon after birth. A single dose of intramuscular Vitamin K is effective in the prevention of classic VKDB and in ameliorating late VKDB. Thus, Vitamin K prophylaxis would prevent morbidity and mortality due to bleeding in neonates.

Neonatal Vitamin K prophylaxis is supported by WHO and professional bodies such as the American Academy of Pediatrics and Canadian Pediatric Society. The concerns regarding Injection Vitamin K-enhancing cancer have been reported to be unfounded. Likewise, there is no risk of hyper bilirubinemia in newborn if used in the recommended dose.

Facility based newborn care training manual of MoHFW recommends that all newborns weighing more than 1000 gm should be given 1 mg of Vitamin K intramuscularly after birth (i.e. the first hour by which infant should be in skin-to-skin contact with the mother and breast feeding is initiated). For babies weighing less than 1000 gm, a dose of 0.5 mg is recommended.



Purpose

The purpose of these guidelines is to:

- Provide the rationale and define the protocols for administration of Injection Vitamin K.
- Promote the use of Injection Vitamin K in all newborns delivered in both public and private health facilities at all levels including medical colleges and tertiary care centres.

Recommendations

1. All newborns delivered in health facilities at all levels including a sub-centre should receive Vitamin K prophylaxis.
2. Vitamin K prophylaxis is given as a single dose IM injection soon after birth. (Once the newborn is in skin-to-skin contact with the mother and breast feeding is initiated).
3. All newborns with birth weight of 1000 gm or more should be administered 1 mg of Vitamin K IM while those weighing less than 1000 gm should receive 0.5 mg dose.
4. Injection Vitamin K should be given IM on the antero-lateral aspect of the thigh using a 26 gauge needle and 1 ml syringe strictly following safe injection practices.
5. In cases that need urgent referral, Vitamin K prophylaxis may be given at the health facility where referral is made and should be documented accordingly.
6. It should be a routine practice to record the date and dose in the Labour Room/OT registers, neonatal case sheets, and referral/discharge slip.
7. Facility in-charge should ensure that medical and nursing staff will administer and document the use of prophylactic Vitamin K to all newborns.

Bleeding in a newborn is a danger sign and may also occur due to causes other than Vitamin K deficiency. In case the newborn has any bleeding manifestation, appropriate referral and management should be instituted promptly as such cases may require blood products and supportive care.

8. All facilities will ensure regular supplies of Vitamin K preparation, syringes, etc.
9. Records of Injection Vitamin K administration should be validated from delivery room registers, case sheets, discharge tickets, and referral registers during routine monitoring visits. This information will be finally transferred into MCTS.

Drug Preparation, Dosage and Administration

1. Vitamin K1: The recommended preparation for use is Vitamin K1 (Phytonadione injectable emulsion), which possesses the same degree of activity as the naturally occurring Vitamin K. The pharmacological action of Vitamin K is to promote the synthesis of Vitamin K-dependent clotting factors (factor II, VII, IX and X) in the liver.
2. Preparation: There are two commonly available preparations in the market:
 - a. 1 mg/1 ml
 - b. 1 mg/0.5 ml
3. States may go for any of the two preparations depending on the availability. Under no circumstances should the state procure the preparation of Injection Vitamin K containing 10 mg/ml.
4. Storage: Injection Vitamin K does not require refrigeration and can be stored at room temperature. As it is thermo stable, no additional expenditure on cold chain maintenance is needed.



5. Dosage: Injection Vitamin K 1 mg per 1 ml or 0.5 ml aqueous preparation.
6. Site of injection: Antero-lateral aspect of the thigh. In case any vaccination being given at birth such as Hep B then they should be given in separate thighs.
7. Logistics: Disposable Syringes (1 ml) and needles (26 G) for administering the injection.

Implementation Steps at the State Level

States must ensure the following:

1. Communication regarding routine use of Injection Vitamin K prophylaxis in newborn reaches at all delivery points including sub-centre and private health facilities.
2. Injection Vitamin K is enlisted in the Essential Drug List and rate contract ensured.
3. The preparation of Injection Vitamin K of 1 mg/ml or 1 mg /0.5 ml is procured so that the standards of practice is uniform at all levels and there is no confusion regarding the dose of the injection.
4. Adequate supplies are made available at the delivery point at all levels in the public health system.
5. During routine field visits for supervision, state officials must look into availability of logistics and implementation of this activity by checking delivery room trays and registers.

Implementation Steps at the District Level

1. District Chief Medical Officer will orient Block Medical Officer In-charge and Facility In-charge regarding use of Injection Vitamin K in all facility births, who in turn will communicate the same to ANMs.
2. Adequate supply of Injection Vitamin K should be ensured at all delivery points.
3. Service provider at the delivery point should regularly estimate the requirement and reports on the stock out situation if it happens.
4. Estimation of the requirement of Injection Vitamin K can be done as below:
 - a. Number of vials required = Number of live births at a delivery point.
 - b. Wastage factor for estimation can be added up later depending on the usage.
5. Safe injection practices to be ensured by all service providers. Disposal of syringes and needles should be done as per the waste disposal and management protocols.
6. The record of administration of the injection is to be maintained in the Delivery Register by the person administering and also to be recorded in baby case sheet if injection is given in postnatal ward/SNCU/NBSU.
7. The referral/discharge slip should also mention the administration of injection. Injection Vitamin K availability and usage is to be monitored during supportive supervision and block monitoring.



Key Messages

Use of Injection Vitamin K Prophylaxis in Newborns

Who will receive?

All newborns delivered in the facilities at all levels (both public and private)

Preparation to be used:

Injection Vitamin K1 (Phytonadione): a) 1 mg/1 ml; b) 1 mg/0.5 ml

Dose to be given:

- Birth weight 1000 gm or more: 1 mg
- Birth weight less than 1000 gm: 0.5 mg

Site and route of injection

- Antero-lateral aspect of the thigh, intramuscular injection

Who will give?

- Medical Officer, staff nurse or ANM

Where it will be given

- In labour room
- It can be given in post natal ward if missed in labour room
- In case of referral the injection should be given at the SNCU/NBSU.

When the injection will be given

- Soon after delivery, ensuring skin-to-skin contact with mother and initiation of breast feeding
- Not later than 24 hours of birth

Logistics required

- 26 gauge needle and 1 ml syringe

Storage

- Room temperature in a dry place

Recording

- Labour room register
- Case sheet
- Referral slips
- Discharge ticket of the newborn

Poster Prototype



Use of Injection Vitamin K Prophylaxis in Newborns

Who will receive? <p>All newborns delivered in the facilities at all levels (both public and private)</p>	Preparation to be used <p>Injection Vitamin K1 (Phytonadione):</p> <ol style="list-style-type: none">1 mg/1 ml1 mg/0.5 ml	Dose to be given <ul style="list-style-type: none">Birth weight 1000 gm or more: 1 mgBirth weight less than 1000 gm: 0.5 mg
Site and route of injection <ul style="list-style-type: none">Antero-lateral aspect of the thigh, intramuscular injection	Who will give? <ul style="list-style-type: none">Medical Officer, staff nurse or ANM	Where it will be given <ul style="list-style-type: none">In labour roomIt can be given in post natal ward if missed in labour roomIn case of referral the injection should be given at the SNCU/NBSU.
When it will be given <ul style="list-style-type: none">Soon after delivery, ensuring skin-to-skin contact with mother and initiation of breast feedingNot later than 24 hours of birth	Logistics required <ul style="list-style-type: none">26 gauge needle and 1 ml syringe Storage <ul style="list-style-type: none">Room temperature in a dry place	Recording <ul style="list-style-type: none">Labour room registerCase sheetReferral slipsDischarge ticket of the newborn

Specifications for printing poster:

- Size: 17 X 22 inch
- Paper: 170 gsm Imported Art Paper (Matte)
- Colours: 4

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