TREATMENT COMPLICATIONS

Inhibitors

- Allo
- Clin
  rout
- Inci
- Risl
  race
  gen
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or FIX

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Hemophilia

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History

- Best known of the hereditary bleeding disorders.
- First coined by *Schonlein* in 1820s.
- Originally termed "*Haemorraphilia"* i.e. love for haemorrhages but over time contracted to *Hemophilia.*
- Hemophilia is often called the disease of kings because it was carried by many members of Europe's royal family. Queen Victo of England was a carrier of hemophilia.

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Disease burden

- Worldwide, the number of hemophiliacs is about the size of the city of St. Louis.
- The World Federation of Hemophilia says about three-fourths of those 400,000 hemophiliacs don't get any treatment.
- The yearly cost of blood-clotting treatments can run to $50,000 or more per individual.

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DEMOGRAPHY and INCIDENCE

- Recognised in all areas of world.
- Hemophilia A - 2nd most common of the inherited coagulation disorders.
- Incidence of Hemophilia A - 1 / 5000 live male births.
- Hemophilia B - 1 / 30000 live male births.

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- Risk … age, race … severe gen …
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TYPES

Disease	Factor deficiency	Inheritance
Hemophilia A	VIII	X linked recessive
Hemophilia B	IX	X linked recessive
Hemophilia C	XI	Autosomal recessive
Parahemophilia	V	Autosomal recessive

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International nomenclature for factor VIII based on recommendations of the International committee on Thrombosis and Haemostasis

Definition	International nomenclature	Outmoded synonyms
Protein lacking or aberrant in hemophilia A	Factor VIII	Anti hemophilic factor
Functional property of factor VIII that is deficient in hemophilia A and measured using coagulation assays.	Factor VIIIc	Factor VIII coagulant activity
Antigenic property of factor VIII that is measured by immuno-assays.	Factor VIIIAg	Factor VIIIcAg

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ACTIVITY

- Defined as the activity present in 1 ml of fresh plasma from normal donors.
- Expressed in terms of **units.**
- Concentration of all coagulation factors in native plasma is thus 1 U/ml or 100 U/dl or 100% activity**.**
- **Levels in blood bank plasma- 80 U/dl because of dilution with anticoagulants**.
- Normal factor VIII and IX activity in patients older than infants range between 50% -150%.

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The severity of hemophilia is defined by the measured level of clotting factor activity.

	Distribution	Clotting factor activity
Severe hemophilia	50%	<1%
Moderate hemophilia	10%	1-5%
Mild hemophilia	30-40%	5-40%

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Pathophysiology

- The classic representation of hemostasis shows factor VII together with tissue factor activating factor X.
- Recent studies suggest that the primary physiologic pathway of factor X activation by tissue factor and factor VII is through the activation of factor IX.
- Activated factor IX complexes with factor VIIIa ,calcium and phosphatidylserine on physiologic membranes to generate factor Xa

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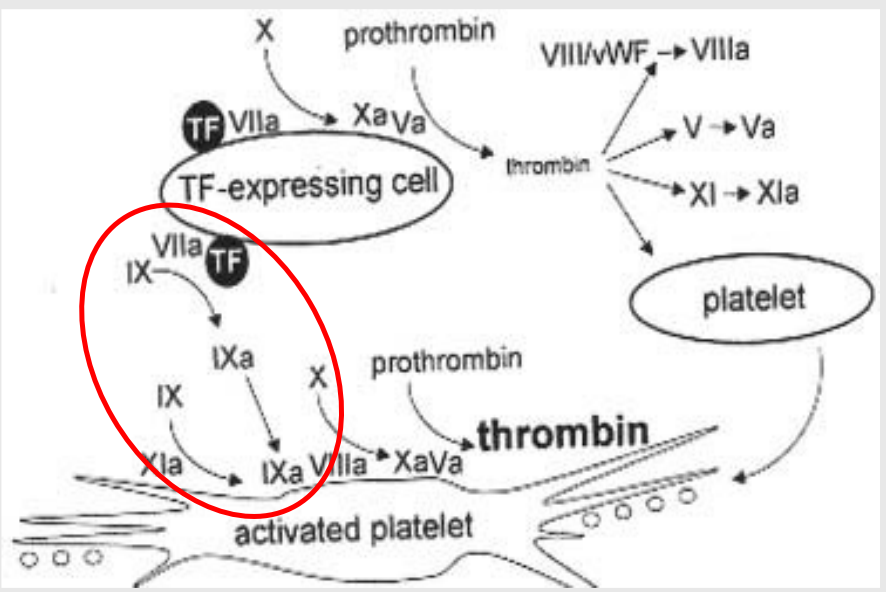

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- Thus, physiologically, the tissue factor pathway of factor X activation requires factor VIII and IX , and the absence of either protein severely impairs the ability to generate thrombin and fibrin.
- The division of hemostasis into distinct intrinsic and extrinsic pathways is no longer accurate.
- Because thrombin generation in hemophilia is markedly delayed, haemorrhage occurs after minimal or unknown trauma. Also the clot formed is friable making rebleeding common.

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Genetics

- X-linked recessive inheritance.
- 30% of hemophilias present as spontaneous mutations.
- Gene for FVIII or IX located on fragile and mutation prone region of X chromosome.
- Most common mutation of FVIII gene - inversion of intron 22.(accounts for 45% cases of severe hemophilia)
- Moderate and mild severity hemophilia A are mainly the result of missense mutations.

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Hemophilia in females

- Very rare.
- Following genetic mechanisms-
  - Lyonization of factor VIII or IX alleles in carriers.
  - Hemizygosity of X chromosome in females with Turner's syndrome.
  - Female progeny of hemophilia carriers & affected haemophiliac male.

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CLINICAL MANIFESTATIONS

- bleeding can happen anywhere in the body.
- following an injury / surgery or spontaneous.

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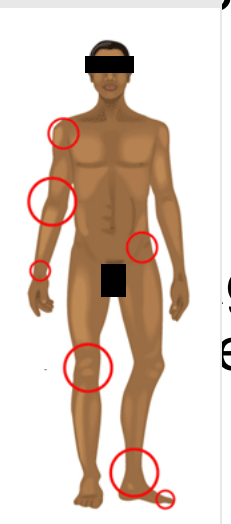
CLINICAL MANIFESTATIONS

Musculoskeletal bleeding

- Deep bleeding into joints and muscles is the hallmark.
- Begin when the child reaches the toddler age.
- In toddlers ankle is the most common site.
- Later knees and elbow become the most common sites.
- preceded by an aura.



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Target joint

- A particular joint that has experienced repeated bleeds.
- at least 4 bleeds within a 6 month period (USA),
- at least 3 bleeds within a 3 month period (Canada).

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Iliopsoas bleeding

- Particularly troublesome,
- Vague abdominal and upper thigh discomfort and a characteristic gait (hip is flexed and internally rotated).
- Diagnosis confirmed by USG or CT.

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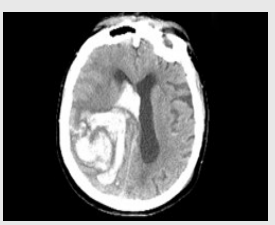
Life threatening haemorrhages

- Intracranial haemorrhage, bleeding into and around the airways and exsanguinating haemorrhage.



- Treatment requires **achieving a factor level of 100 U/dL,** maintenance of adequate hemostatic levels (>50-60 U/dL) for minimum 14 days, and a more prolonged period of prophylactic therapy for additional 1-2 wk.

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Miscellaneous haemorrhages

Hematuria- May arise spontaneously. Therapy consists of bed rest and increased fluid intake. If not controlled in 1-2 days then factor replacement. *Avoid antifibrinolytic agents* because of the risk of intra-ureteral clot formation.

Traumatic bleeding- bleeding may persist as slow continuous ooze for days to months or it may be massive and life threatening. Delayed bleeding is common.

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Venipuncture, if skilfully performed is without danger. After s.c., i.d., and small i.m. injections apply firm finger pressure for at least 5 min. *Large i.m. injections should be avoided.*

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Hemophilic arthropathy

Three phases

1. Following first episodes of hemarthrosis absorption of blood is incomplete, the retained blood produces chronic inflammation. Iron is deposited into the synovium and chondrocytes of the articular cartilage.

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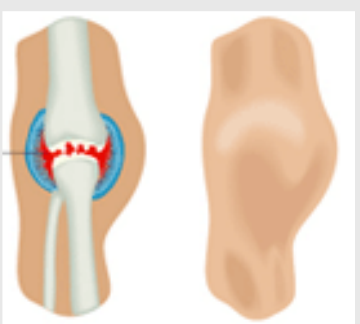

2. Chronic proliferative synovitis- characterised by presence of chronic synovitis, pain, fibrosis and progressive joint stiffness.

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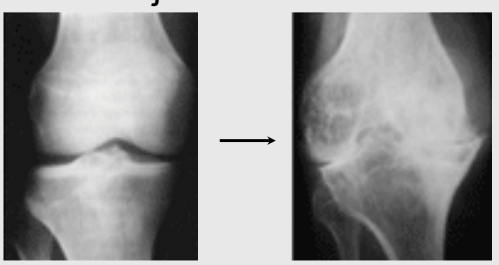
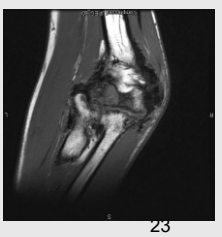
3. Chronic hemophilic arthropathy-characterised by progressive and erosive destruction of joint cartilage, narrowing of joint space,subchondral cyst formation, and eventual collapse and ankylosis of the joint.



MRI is superior to standard radiography for assessment of early arthropathy.



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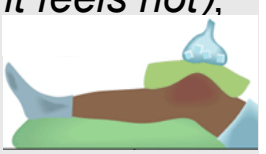
Management of hemophilic arthropathy.

- Analgesics *(acetaminophen alone or with codeine),* **ice packs** *(5 minutes on, 10 minutes off, for as long as the joint feels hot),* avoidance of weight bearing and immobilisation.



- Factor replacement- most important

- Synovectomy- indications

types → Arthroscopic
Chemical
Radiosynovectomy

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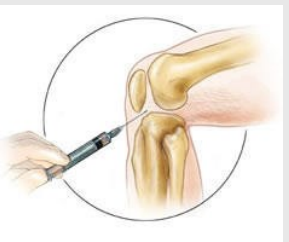
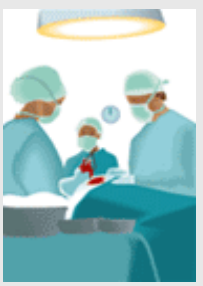
Management of hemophilic arthropathy.

- Arthrocentesis
  - Reserved modality
  - Indications



- Physiotherapy

- Reconstructive surgery



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LABORATORY EVALUATION

Activated partial thromboplastin time

- prolonged to 2-3 times
- In mild to moderate factor IX deficiency it may be normal. Thus if hemophilia is suspected, a factor IX assay should be performed even if the PTT is normal.

APTT correction studies

- With control plasma- confirms factor deficiency and not circulating inhibitors as the cause of APTT prolongation.
- With FVIII deficient plasma (from known patients) - suggests FIX deficiency.
- With FIX deficient plasma (from known patients) - suggests FVIII deficiency.

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Factor assays

- Types
- To determine diagnosis
- Monitor treatment
  - Performing pre and post-infusion clotting factor levels.
  - Factor levels prior to surgery.
- To test quality of cryoprecipitate

Detection of inhibitors

- When to suspect- PTT not correcting to normal when mixed with normal plasma and incubated for 120min
- One **Bethesda unit** is defined as the amount of antibody that will inactivate 50% of the normal FVIII or FIX in 2hr when the residual FVIII or FIX level is between 25 and 75 U/dL.

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Carrier state and Genetic testing

Three approaches:

1. Patient and family history;
2. Coagulation-based assays;
3. DNA testing.

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Carrier state and Genetic testing

- *A woman is a definite carrier if* (i)her father has hemophilia, (ii)she has one son with hemophilia and a 1st degree male relative with hemophilia, (iii)she has two sons with hemophilia.

- *A possible carrier if* (i)she has one or more maternal relatives with hemophilia, (ii)she has one son with hemophilia & no other affected relative.

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- Carrier status based solely on factor levels - not reliable, significant overlap.
- In severe hemophilia A, perform intron 22 gene inversion analysis and, if negative then proceed with full FVIII gene sequencing.
- In mild to moderate hemophilia A, full sequencing of the FVIII gene is recommended.
- In hemophilia B, perform full sequencing of FIX gene.

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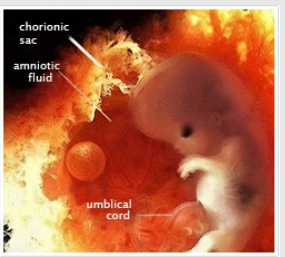
Prenatal diagnosis

- Offered when termination of pregnancy would be considered if affected fetus identified.
- Obtain chorionic villi samples in 10th-11th gestational week and perform direct genotype testing.
- Test duration. 1wk / 2wk



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TREATMENT

Fundamentals

- **Replacement therapy-** Replacement of FVIII or IX to hemostatically adequate plasma levels for prevention or treatment of acute bleeding is the basis of the management of hemophilia.
- Knowledge of the half-life, volume of distribution, patient's inhibitor status and appropriate replacement material is necessary.

Table-Biodynamic properties of coagulation factors of concern in replacement therapy

Factor	Hemostatic level (U/dL)	Biologic half life (hr)
FVIII	25-30	12
FIX	15-30	24

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- Calculation of dose
  - Dose of FVIII (units) = (percent desired rise in plasma FVIII) **x** (body wt) **x** 0.5
  - Dose of FIX (units) = (percent desired rise in plasma FIX) **x** (body wt)
  - Dose of rFIX(units) = (percent desired rise in plasma FIX) **x** (body wt) **x** 1.4
- Types of factor replacement
  - Treatment on demand.
  - Prophylaxis.

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Treatment on demand

- For mild to moderate haemorrhages, achieve FVIII levels of 30-40 U/dL or FIX levels of 30 U/dL.
- For life threatening haemorrhages, immediately correct factor level to 100-150 U/dL and maintain level between 80-100 U/dL for 5-7d followed by vigorous maintenance.

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Type of hemorrhage	Hemophilia A	Hemophilia B
Hemarthrosis	40 IU/kg on day1; then 20 IU/ kg on days 2, 3, 5 until joint function is normal or back to baseline. Consider additional treatment every other day for 7-10 days. Consider prophylaxis.	60-80 IU/kg on day 1; then 40 IU/kg on days 2, 4. Consider additional treatment every other day for 7-10 days. Consider prophylaxis.
Muscle or significant subcutaneous hematoma	20 IU/kg; may need every-other-day treatment until resolved.	40 IU/kg; may need treatment every 2-3 days until resolved.
Mouth, deciduous tooth or tooth extraction	20 IU/kg; antifibrinolytic therapy; remove loose deciduous tooth.	40 IU/kg; antifibrinolytic therapy; remove loose deciduous tooth.
Epistaxis	Apply pressure for 15-20 min; pack with petroleum gauze; give antifibrinolytic therapy; 20 IU/kg if this treatment fails.	Apply pressure for 15-20 min; pack with petroleum gauze; give antifibrinolytic therapy; 30 IU/kg if this treatment fails.
Major surgery, life threatening hemorrhage	50-75 IU/kg, then initiate continuous infusion of 2-4 IU/kg/hr to maintain FVIII >100 IU/dL for 24hr, then give 2-3 IU/kg/hr continuously for 5-7d to maintain the level at >50 IU/dL and an additional 5-7d at a level of >30 IU/dL	120 IU/kg, then 50-60 IU/kg every 12-24 hr to maintain FIX >40 IU/dL for 5-7 d and then >30 IU/dL for 7 d.
Hematuria	Bed rest; 1.5 times maintenance fluids; if not controlled in 1-2 d, 20 IU/kg FVIII.	Bed rest; 1.5 times maintenance fluids; if not controlled in 1-2 d, 40 IU/kg FIX
Prophylaxis	20-40 IU/kg FVIII every other day to achieve a trough level of ≥ 1%.	30-50 IU/kg FIX every 2-3 days to achieve a trough level of ≥ 1%.

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Prophylactic factor VIII therapy-Evidence

The NEW ENGLAND JOURNAL of MEDICINE

- Manco-Jonson et al in their prospective, randomised, controlled clinical trial showed **83% reduction in risk for joint damage (evaluated by MRI) in the prophylaxis group** as compared to on-demand group. In 14% cases of MRI changes, there was no evidence of any previous clinical hemarthrosis.

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Prophylactic factor VIII therapy-Evidence

- Fischer et al in their long term outcome study over 22yr showed that **prophylaxis improves clinical outcome without significantly increasing treatment cost.**

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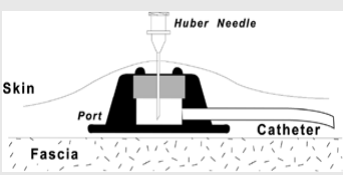
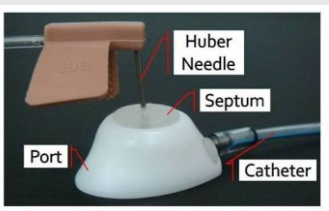
Prophylactic factor VIII therapy

- Administered by subcutaneous access port of a central venous line.
- **Dose of 20-40 U/kg of FVIII administered every other day or thrice weekly**. Dose and rate adjusted to ensure that nadir before next infusion is >1U/dL.
- Prevents spontaneous bleeding; haemorrhages caused by trauma may still require additional replacement.





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Prophylactic factor VIII therapy

- Primary prophylaxis - therapy initiated in young patients who have hemophilia before joint damage
- High cost of primary prophylaxis – hindrance for developing countries. However, the long term cost savings may be greater with primary prophylaxis as joints are preserved, lives are more productive, expensive surgical interventions avoided.

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When to start primary prophylaxis ?

- no consensus!!
- **Start before 3 years of age,** usually around 14-18 mo, at the time that the child begins to walk.

Secondary prophylaxis

- In patients with target joints who are having recurrent events.
- Coagulation factors are administered as in primary prophylaxis but over limited period of 3-6 months.

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Tailored prophylaxis

- Basic idea.
- Tailored to patient's bleeding pattern, joint involvement and individual needs.
- Once weekly infusion of factor concentrate has been studied thus reducing the need for CVC placement.
- The indwelling venous access devices are the cause of most of the complications associated with prophylaxis (Systemic infections, catheter-related thrombosis etc.)
- The long term effect on joint outcome using this approach warrants further scrutiny.

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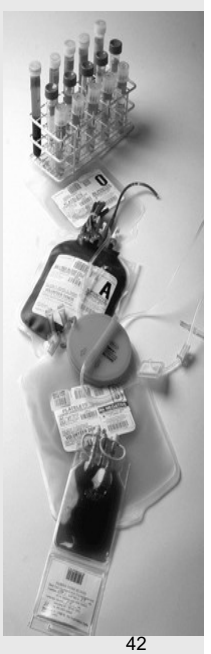
TREATMENT PRODUCTS



Plasma

- Diff. b/w Fresh frozen and frozen.
- 1 U FFP contains about 160-250ml plasma with activity of ~80%.
- Rate and total dose limited by the risk of acute or chronic circulatory overload.
- How to use
  - Thaw.
  - Transfuse over how many minutes.
  - Reusing after thawing. What about ½ or 1/3 unit FFP ?

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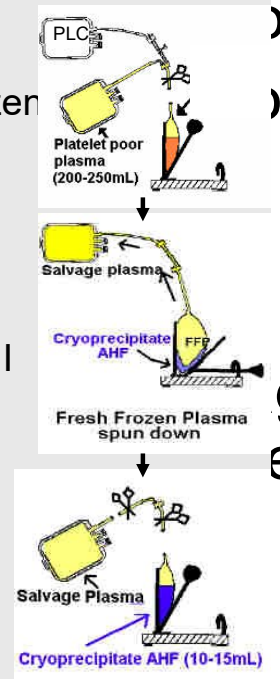
Cryoprecipitate

- Prepared by slowly thawing fresh frozen plasma at 2-4`C, then harvesting the precipitate by centrifugation.
- Cryo prepared from 200ml of FFP contains 80-100 U of FVIII, ~250mg fibrinogen and useful amounts of FXIII and vWF per 10-15ml of precipitate.
- Use thawed cryo within 4hr.
- Can be stored at -18`C for 1yr.



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Factor concentrates

- Types
  - On basis of source of origin.
  - On basis of purity:
    intermediate, high, ultrahigh.
- The safety data to date favour recommendation to exclusively use recombinant products.
- Infuse FVIII by slow IV push at a rate not to exceed 100 units per minute in children.

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ADJUVANT TREATMENT OPTIONS

Desmopressin (DDAVP)

- Increases plasma FVIII and vWF levels.
- In mild an moderate Hemophilia A who have shown response in therapeutic trial.
- iv dose - 0.3mcg/kg, in 25-50mL NS 20-30 min.
- For OPD management intranasal route. Dose -150mcg (1 puff) for<50kg and 300mcg (1 puff in each nostril) >50kg
- Tachyphylaxis
- S/E - Headache, flushing ,Hyponatremia
- Peak effect iv form - 30-60 min; intranasal form 60-90 min

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Antifibrinolytic therapy

- Inhibits fibrinolysis of thrombus by plasmin.
- Uses - mucosal bleeding, oral, nasal and menstrual loss.
- Tranexamic acid -effective topically as a mouth wash
- C/I in hematuria.

Dose

- Tranexamic acid
  - oral- 25 mg/kg/dose every 6-8hr.
  - iv - 10 mg/kg/dose every 6-8hr.
- EACA
  - Oral - 100-200mg/kg initially followed by 50-100mg/kg/dose every 6hr
  - iv - 100mg/kg/dose every 6hr.

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TREATMENT COMPLICATIONS

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TREATMENT COMPLICATIONS

Inhibitors

- Alloantibodies directed against FVIII or FIX
- Clinical hallmark- failure to respond to routine replacement therapy.
- Incidence - hemophilia A ~30%;
  hemophilia B ~3%.
- Risk factors- severity of hemophilia, age, race, family history of inhibitors and severe gene defects.
- Low titer (<5 BU); usually transient.
- High titer (>5 BU); persistent.
- Screen once every 3-12 months or every 10-20 exposure days and prior to surgery or when clinical response to adequate treatment is sub-optimal.

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Management of inhibitors

- Low titer- high dose factor replacement.
- High titer
  - continuous FVIII infusion.
  - bypassing agents- recombinant factor VIIa or activated prothrombin complex concentrates.
  - Immune tolerance induction (ITI)
  - Rituximab- limited data (only 18 patients)

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TREATMENT COMPLICATIONS

Inhibitors

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Immune Tolerance Induction

- Immune system desensitisation technique intended to eradicate inhibitor.
- No general agreement on optimal dosage and frequency of dosage for ITI. A trial is ongoing to compare 50 IU/kg three times a week to 200 IU/kg daily.
- Success of ITI ~90% over 6-12 months for alloFVIII antibody inhibitors.
- Consolidate inhibitor eradication with prolonged prophylaxis.

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Transfusion transmitted infections

- Viral attenuated plasma-derived factor concentrates are free from lipid enveloped viruses viz. HIV, Hep B, Hep C.
- Non-lipid enveloped viruses - Hep A, parvovirus B19 are not susceptible to these techniques, outbreaks reported.
- Recombinant factor concentrates contain albumin as stabiliser- theoretical risk of transmission of prions (no case ever reported).
- Immunization to hepatitis B and A is important for all persons with hemophilia and can be given s.c. not i.m.
- Family members handling treatment products should also be vaccinated.

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NEWER TREATMENT MODALITIES

Activated Prothrombin complex concentrates

- Have increased amounts of activated FVIIa, factor X & thrombin.
- APCC are effective even in patients with high titer inhibitors.
- risk of thrombosis.

Polyethylene glycol conjugation (Pegylation)

- Increases size, decreases renal excretion, extends half life.

Polysialic acid polymers

- Forms a “watery cloud” around the target molecule
- Biodegradable.

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Recombinant factor VIIa (rFVIIa)

- Marketed and manufactured by NovoNordisk, Denmark as Novoseven.
- Bypasses the FVIII-dependent step in factor X activation.**
- Primary use- Hemophilia with inhibitors.
- Other uses- control bleeding in traumatic coagulopathies, thrombocytopathies, liver disease, liver transplantation, spontaneous intracerebral hemorrhage and patients undergoing cardiac surgery.
- Dose-90mcg/kg 2hrly till hemostasis.
- Cost-Rs 35000/1.2 mg vial; 75000/2.4 mg vial.

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TREATMENT COMPLICATIONS

Inhibitors

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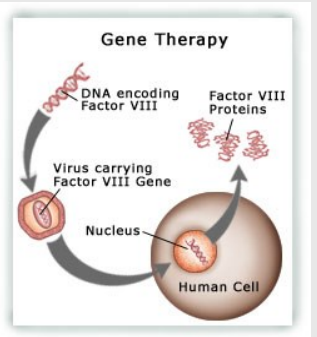
Gene therapy



- Involves transfer of genes that express a particular gene product into human cells.
- Hemophilia-ideal candidate
  - caused by mutations in single identified gene.
  - Wide range of safety if there is an “overshoot”
- To date the promise of gene therapy and a cure for the hemophilia patient have not been realized.
- Continues to be a topic of intense investigation.

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Comprehensive care

- Comprehensive team including the hemophilia specialist, nurse coordinator, social worker, psychologist, physiotherapist, orthopaedic surgeon, primary care physician, financial counsellor and sometimes infectious disease specialist.

- Provided primarily through comprehensive hemophilia treatment centres.

TREATMENT COMPLICATIONS

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Home therapy

- Allows immediate access to treatment.
- Teach- recognizing a bleed, dosage calculation, preparation, storage, and administration of clotting factor, aseptic techniques, performing venipuncture (or access of central venous catheter), record keeping, proper storage and disposal of needles and handling of blood spills

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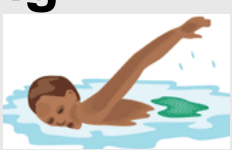
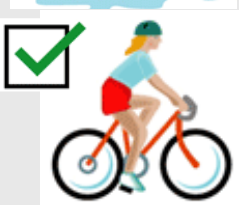
Prevention of bleeding

- Avoid trauma by adjusting their lifestyle.
- Contact sports should be avoided, but swimming and cycling with appropriate gear should be encouraged.
- Avoid use of drugs that affect platelet function viz. NSAIDs.
- Intramuscular injections, difficult phlebotomy, and arterial punctures must be avoided.
- Regular exercise should be encouraged to promote strong muscles, protect joints, and improve fitness





TREATMENT COMPLICATIONS

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Do the 5 !

Do the 5! is a list of 5 things one can do to help live a long and healthy life. The NHF started the idea for Do the 5!

1. Get an annual comprehensive check-up at a hemophilia treatment centre.
2. Get vaccinated - Hepatitis A and B are preventable.
3. Treat bleeds early and adequately.
4. Exercise and maintain a healthy weight to protect the joints.
5. Get tested regularly for blood-borne infections.

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What medical information should be carried by a hemophiliac ?

A person with hemophilia should carry information about his health, including the type of hemophilia, treatment needed, and allergies.

An international medical card is available free through the World Federation of Hemophilia. Tags called Medic-Alert and Talisman are sold in some countries

TREATMENT COMPLICATIONS

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World Hemophilia Day 2009

- Since 1989, patient groups and treatment centres have been coming together on April 17 to celebrate World Hemophilia Day.
- The theme for World Hemophilia Day 2009 is “Together, we care,” which emphasizes the importance of comprehensive care in hemophilia healthcare delivery.

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