VIRAL HEPATITIS

PUBLISHED BY THE VIRAL HEPATITIS PREVENTION BOARD

Fact Sheet - 3 - April 1998

This edition of *Viral Hepatitis* is prepared from material presented at the Viral Hepatitis Prevention Board meeting held 2 - 4 July, 1997 in Kiel, Germany.

ENSURING INJECTION SAFETY AND A SAFE BLOOD SUPPLY

World-wide, the transmission of bloodborne infections through unsafe injections, and unscreened blood and blood products are well documented public health problems which demand continuous efforts at improvement.

WHO estimates that world-wide more than 1 billion injections are given each year. Analysis at the WHO suggests that at least 50% of the injections given in some parts of the developing world are unsafe, and that more than 8 million HBV infections and almost 2 million HCV infections occur each year from unsafe injections.

The exact magnitude of the problem in Central and Eastern Europe and the NIS is unknown, and the situation varies considerably by country, but transmission by unsafe injections is thought to be a major mode of HBV and HCV transmission in the region. The problem is complicated as a consequence of the enormous demand for injections by patients, and by a high proportion of unnecessary injections given both inside and outside of formal medical settings.

Injection safety is imperative in any immunization programme; failure to ensure the safety of all injections can have far-reaching negative consequences and bring vaccination programmes in danger.

Infections caused by percutaneous exposure to blood through unscreened blood and blood products are a serious problem in many parts of the world. Donation screening and inactivation procedures have essentially eliminated HBV and HCV transmission from blood or blood products in industrial countries, but the lack of organized transfusion services and the high cost of reagents (particularly in the case of HCV) have made it difficult to eliminate bloodborne transmission of HBV and HCV in many developing countries and transitional economies.

What follows are practical guidelines for delivering safe injections particularly in the context of immunization programmes, and for ensuring the safety of the blood supply.

Ensuring the Safety of Injections

The following recommendations are aimed at ensuring the safety of injections administered as part of an immunization programme or given for therapeutic reasons. In particular, the recommendations apply to hepatitis B immunization.

Injections for immunization
According to WHO recommended policy:

An injection should only be given if it is necessary - and each injection that is given must be safe.

- An injection for immunization is necessary.
- An immunization injection is safe when the vaccine is injected with the appropriate equipment and according to the recommended procedures for injection, sterilization and disposal.

Equipment for delivering injections
Auto-destruct syringes with fixed needles, standard disposable syringes and needles, and sterilizable syringes with needles can all be used to administer hepatitis B vaccine. The auto-destruct syringe is recommended when conducting mass immunization campaigns as it presents the lowest risk of person-to-person transmission because is cannot be re-used.

Standard disposable syringes and needles are only recommended where it is guaranteed (as verified by a system of monitoring) that they will be destroyed after a single use; re-use of disposable syringes and needles places the general public at high risk of infection.

Vaccinating with a jet gun is not recommended as the risk of transmission of bloodborne infections cannot be excluded. In addition, it is unlikely that jet guns can be used with adjuvanted vaccines.

Collecting equipment in safety containers
Puncture resistant containers for collecting and disposing of used disposable and auto-destruct injection materials as well as worn out sterilizable equipment must be used in all immunization activities. These containers help protect healthcare staff and the public from the risk of exposure posed by contaminated needles.

Recommended injection practices
The site of the injection and the method of administering the vaccine are critical factors in achieving maximal seroconversion rates. Intramuscular injection is recommended, although injections can, under certain circumstances, be given subcutaneously or intradermally.

Intramuscular injection produces highest seroconversion rates
Children (≥ one year of age) and adults should receive injections in the deltoid muscle of the arm; infants (< one year of age) should be given the injection in the quadriceps muscle. Persons vaccinated in the gluteal muscle have lower seroconversion rates and antibody titres than do those who receive all of their injections intramuscularly in the deltoid muscle.

The needle used must be long enough to penetrate subcutaneous tissues and enter the belly of the muscle, and it should be introduced at right angles to the surface of the skin.

Reduced titres with intradermal injections
Because it requires 1/5 to 1/10 the normal dose of vaccine, intradermal injection is sometimes used in an effort to lower the costs of vaccination. There are, however, a number of drawbacks to intradermal injections, in particular: significantly reduced anti-body HBs titres, an increased frequency of local reactions, and greater technical difficulty in administering the injection. In addition, HB vaccine is not licensed for intradermal use.

Subcutaneous injections for persons with impaired coagulation
Subcutaneous injections are also not recommended for routine use because it is thought that the immune response with subcutaneous injections can be slightly impaired. Subcutaneous injections may be used in individuals with impaired coagulation (e.g. haemophiliacs or persons undergoing anticoagulant therapy), although it should be noted that subcutaneous injections cause a higher frequency of local reactions, in particular, granuloma at the injection site.

Appropriate disposal of equipment
When using auto-destruct syringes and needles, place each syringe and needle in a puncture-resistant container designed especially for this purpose. If a specialized container is not available, an alternative puncture-resistant container such as a pertol container or a sturdy plastic bottle can be used. **Do not recap the needle.** Do not use disposable syringes and needles from damaged sterile packs or which have passed the manufacturer's expiration date.

Sterilizable syringes and needles
A sterile syringe and a sterile needle must be used for each injection. The correct procedure for cleaning and sterilizing is:

- Flush water through the syringe and needle. Wash disassembled syringes in clean water before placing them in the sterilizer. Use forceps to load syringe components and needles into the sterilizer.
- Steam sterilize reusable needles, syringes and forceps at 121°C-125°C for 20 minutes, according to the manufacturer's instructions. Steam sterilization kills all harmful viruses, bacteria and spores; boiling does not.
- Approved sterilization indicators (time, steam and temperature: TST) must be used for each sterilization cycle.
- Dispose of syringes which leak, become too stiff to use or which have faded graduations. Dispose of needles which are blocked, blunted or hooked. Do not attempt to re-sharpen needles.

Destroying contaminatedequipment
Incineration at a secured compound is the recommended method for disposing of used syringes and needles. If this is not possible, contaminated sharps should be burned in a pit or drum. Do not transfer contaminated sharps from container to container. Incineration or burning should take place as close to the immunization facility as practical, and as soon after the immunization session as possible.

Evaluation of immunization programmes
Regular evaluations of injection practices are necessary. Evaluations should include reviews of injection practices, equipment and the equipment supply system in all vaccination programmes. Adverse events related to injections should be investigated to improve the quality and safety of injections.

Reliable supply of equipment and vaccine
Maintaining a reserve stock of equipment (including syringes, needles, fuel for sterilization, spare parts for the maintenance of steam sterilizers, and puncture-resistant containers) is part of ensuring the safety of immunizations. Adequate budgeting and a system for distributing vaccine and equipment are also necessary components of any successful immunization programme.

Based on information presented by Prof Wolfgang Jilg of the Institute for Medical Microbiology and Hygiene, University of Regensburg, Germany; and on information from the World Health Organization, Global Programme for Vaccines and Immunization, Expanded Programme on Immunization, Safety of injections in immunization programmes, 1996; and the WHO/VHPB publication, Hepatitis B as an Occupational Hazard.

The following is a checklist recommended by the WHO for determining injection safety:

Check the following points and circle "yes" or "no".		
1. Have abscesses occurred at the site of immunization injections?	Yes	No
2. Is there evidence of re-use of syringes and needles without sterilization?	Yes	No
If the answer to any of the above questions (1 or 2) is "yes", injections at this centre are unsafe.		
3. Is the stock of syringes, needles and fuel for sterilization sufficient for at least one week of immunization activities?	Yes	No
4. Is there evidence that contaminated injection materials are destroyed either by burning or by sterilization?	Yes	No
5. Is there a steam sterilizer and heater available and in good working order?	Yes	No
6. Are TST control spots routinely used?	Yes	No
If the answer to any of the questions 3 - 6 is "no", there is a risk of unsafe injections.		

VHPB RECOMMENDATIONS

The transmission of bloodborne infections through unsafe injections and unsafe blood remains a serious public health problem, particularly in some parts of the developing world and in some transitional economies. What follows are practical recommendations from the VHPB on how to deliver safe injections, and how to ensure the safety of the blood supply, specifically in relation to bloodborne hepatitis viruses.

INJECTION SAFETY

The VHPB recommends:

- education of healthcare providers and the public about the dangers of unsafe injections;
- education of healthcare providers and the public on appropriate and inappropriate use of injections;
- insistence that a separate sterile needle and a separate sterile syringe be used for each injection, and then properly disposed of;
- use, wherever possible; of auto-destruct syringes and the provision of adequate supplies of sterile needles, syringes and sterilizing equipment as appropriate;
- routine evaluation of the safety of immunization programmes;
- research into the extent of the problem of unsafe injections in Central and Eastern Europe and the NIS.

BLOOD SAFETY

The VHPB recommends:

- All countries should develop a structured blood transfusion service to ensure the safety of blood through proper donor selection, blood collection and testing, safe use and disposal of equipment, and appropriate use of blood. All donations should be screened for HBsAg and anti-HCV.
- All transfusion services should be routinely monitored for safety.
- Although the most recent and technologically advanced screening assays may not be available in many countries because of financial, logistical or technical constraints, this should not prevent the development of an effective blood screening programme. The undisputed benefits of screening all blood donations far outweigh concerns over the sensitivity of available assays.
- The international community should ensure that countries in greatest need can access the necessary resources to achieve safe blood use. Manufacturers of reagents are urged to make screening tests available at affordable prices to developing countries.

REFERENCES AND FURTHER READING

1. ACIP. General recommendations on immunization. *MMWR*,1989; 38: 205-227.
2. ACIP; Update on adult immunization. *MMWR*, 1991; 40: No. RR12.
3. Epidemiological notes: inadequate immune response among public safety workers receiving intradermal vaccination against hepatitis B - United States, 1990-1991. *MMWR*, 1991; 40: 569-572.
4. Shaw FE et al. The effects of anatomic injection site, age and smoking on the immune response to hepatitis B vaccination. *Vaccine*, 1989; 7: 425-430.
5. US Department of Health and Human Services. Protection against viral hepatitis: recommendations of the Immunization Practices Committee. *MMWR*, 1990; 39(S-2); 1-26.
6. World Health Organization. Global Programme for Vaccines and Immunization. Expanded Programme on Immunization. Safety of injections in immunization programmes. Geneva, Switzerland, 1996; 1-11.
7. WHO/UNICEF Statement on Injection Safety in Mass Campaigns. 1998.
8. Zachoval R et al. Risk of virus transmission by jet injection. *Lancet*, 1998; I:189.

Safeguarding the Blood Supply

Preventing the transmission of bloodborne infections is an indispensable part of ensuring the safety of blood and blood products. The following safety recommendations can be applied to any general blood safety programme, although they are aimed specifically at preventing the transmission of bloodborne hepatitis viruses.

A blood collection system that ensures the safety of the blood supply must be based on a number of cumulative factors:

- **organization** at both the local and national levels;
- **screening**, which includes donor selection and the mainstay of blood safety, laboratory testing;
- **inactivation** of raw plasma and the final product;
- **appropriate** use of blood, an often overlooked but important part of securing blood safety.

The hepatitis B and C viruses are two of the major infectious diseases that can be transmitted by blood transfusions. Both HBV and HCV fulfil all the criteria for transmissibility: the agent is present in the blood, it gives rise to asymptomatic infection, and it is stable in blood and blood products at the conditions under which they are stored.

Organization
An organizational framework at both the national and local levels is the foundation of any blood collection system; a lack of organization and commitment can have far-reaching negative consequences on the safety of the blood supply and on the recruitment and retention of blood donors. At the national level what is needed are: a clear policy, a recognized blood transfusion system, funding and a system of recruitment and retention of volunteer blood donors. Local needs include appropriate systems for donor selection, testing and quality control.

Donor selection
The prime objective behind donor selection is to minimize the risk to patients of acquiring post-transfusion hepatitis. The primary concern is to collect blood only from safe, low-risk donors - those who would be least likely to transmit the virus. However, there is also a responsibility to the donor. For instance, would donation compromise the health of the donor? Furthermore, failure to detect an infected donor could increase the potential risk of inapparent transmission to partners and close contacts.

Donor selection is based on visual examination and questioning of the donor. Individuals would be at higher risk for infection as a result of occupation, lifestyle, certain behaviours or certain illnesses. Although donor selection is an important first step in the process, it is not fail-safe. Furthermore, it relies on the right questions being posed, and on donors answering those questions truthfully. It is important to communicate to donors what "high risk" means, what information is required and why that information is significant.

Laboratory screening
Donor selection is essential, but it has limitations, and it does not replace laboratory screening. Laboratory screening is undertaken to identify individuals with serologic evidence of HBV and HCV, as well as HIV. In the case of hepatitis B, donations are screened for the presence of HBsAg (hepatitis B surface antigen), and in some countries, for anti-HBc (hepatitis B core antibody) as well.

Viral inactivation
Viral inactivation procedures performed on raw plasma and on the final product are essential in the production on large pool products. Viral inactivation procedures include, among others: heat treatment (wet and dry); pasteurization (albumin); and solvent treatment of plasma (immunoglobulins).

Appropriate use of blood
Appropriate use of blood is an important aspect of blood safety that is often overlooked; and appropriate use of blood is a major issue in many countries. Excessive and unnecessary use of blood not only exposes individuals to unnecessary risk, but it also uses up a valuable resource, often in countries where blood is scarcest.

In many cases, volume expansion is all that is required, and this can be addressed by the use of synthetic volume expanders in place of blood. Similarly, blood salvage techniques have improved to the point that, even in cases of severe blood loss, a salvage system can be used along with a minimal amount of blood. Even where blood is clearly required, the number of units transferred should be examined clearly to limit unnecessary transfusions. Education of medical and technical staff on the appropriate use of blood should be part of any blood safety programme.

The window period
There are rare situations in which infectious donations may not be detected by laboratory screening. All infectious agents have a "window period", defined as the period of time between the point of infection and the first appearance of detectable circulating markers of infection. The serological window period for HBV is considered to be between 25 and 60 days. Donations made during this period may not be detected by screening tests and may be infectious. The length of this period depends on the type and the sensitivity of the screening test used.

Threats to blood safety
Although donations made during the window period of infection account for some donor-transmitted infections, they represent a small percentage of transfusion-transmitted cases

of hepatitis B. More common threats to blood safety are the failure to screen blood at all and the failure to remove and destroy donations which have been identified as infectious.

Clearly the biggest threat to blood safety is the failure to screen blood. While the most common reason given for this is the lack of financial resources to purchase kits and implement testing systems, another often overlooked explanation for the failure to test is a lack of national commitment to a blood screening programme. This may result in constant crisis situations in which there are acute shortages of blood: when a patient is urgently in need of blood, there is simply no time for testing donations. In these situations, resources are best spent on donor retention and recruitment.

System failures

Infectious donations may also fail to be identified through inadequate administration or interpretation of diagnostic assays, or through clerical errors when handling the results of testing. The most common clerical error cited is the disposal of the wrong donation. Again, these failures can be overcome by instituting a framework and adhering to quality programmes.

Conclusions

The aim of transfusion services world-wide is to provide blood and blood products which are free of infectious agents. Clear differences in the risks of post-transfusion infection can be seen between countries with developed healthcare systems and those with poorly developed healthcare systems. In countries where there is a commitment to and funding for a structured national blood collection service, the risk of acquiring post-transfusion hepatitis B and C is very low. In countries with poorly developed healthcare systems, this is not usually the case. Although economics is often cited as the main reason for the failure to ensure blood safety, this is only part of the problem. A safe blood supply can be achieved only if a blood collection and transfusion system is based on: an organized system at both the national and local levels; donor selection; laboratory screening; inactivation of raw plasma and the final products; and the appropriate use of blood (only when it is indicated medically).

Threats to Blood Safety

- inadequate recruitment and retention of volunteer blood donors
- no donor selection
- failure to screen blood
- failure of testing to identify infectious donations during the "window period" of infection
- failure to destroy infectious donations
- inappropriate use of blood
- shortage of blood supply

Based on information presented by Dr Alan Kitchen of the National Blood Service, London, UK.

The Viral Hepatitis Prevention Board is part of the Centre for the Evaluation of Vaccination, a designated WHO Collaborating Centre. The VHPB works under the auspices of the Society of Occupational Medicine and the European Public Health Association. The Board is supported in part by grants from the pharmaceutical industry (SmithKline Beecham Biologicals, Pasteur Mérieux MSD, Merck Sharpe & Dohme) but has strict scientific independence.

Viral Hepatitis is published and produced by the VHPB, and printed by Jacqmain Ltd, Antwerp, Belgium.

For further information please contact the VHPB Executive Secretariat at:
The VHPB Executive Secretariat
Centre for the Evaluation of Vaccination
WHO Collaborating Centre for Prevention and Control of Viral Hepatitis
Epidemiology and Community Medicine
University of Antwerp • Universiteitsplein 1 • B-2610 Antwerp, Belgium
Tel 32 (0) 3 820 25 23 Fax 32 (0) 3 820 26 40
http://vhpb-www.uia.ac.be/vhpb/