HOSPITAL SEGAMAT, ISSUE 04/2016

PHARMACY Bulletin

POST EXPOSURE PROPHYLAXIS

An exposure is defined as a percutaneous injury, or contact, of mucous membrane or non-intact skin with blood, tissue, or other body fluids that are potentially infectious. Percutaneous exposure occurs when the skin is cut or penetrated by needles or other sharp instruments (for example: scalpel blade, trochar, bone fragment, or tooth) while mucocutaneous exposure is when blood or other body fluids contaminate the eye(s), the inside of the nose or mouth, or an area of non-intact skin[1].

- The most common form of injuries amongst Health Care Workers (HCW) are needlestick injuries. In Malaysia, the Occupational Health Unit in the Ministry of Health had reported an incidence rate of 4.7 needlestick injuries per 1,000 HCW's in 2005[1].

Health Care Workers (HCW) can be classified as persons whose activities involve contact with patients, or blood or other body fluids from patients in a healthcare, laboratory or public-safety setting[2].

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References
1. Guideline to Occupational Exposure to HIV, HBV, and HCV and recommendation for PEP. MOH Malaysia 2007.
2. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. CDC 2001.
3. Post-exposure prophylaxis to prevent HIV infection, WHO factsheet. 1 December 2014

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IMMEDIATE ACTION AFTER EXPOSURE

⇒ Percutaneous injuries, blood should be expressed out by squeezing the tissues adjacent to the wound and immediately washing it thoroughly with soap and water. If necessary the wound should then be disinfected and dressed.

⇒ For mucosal exposures e.g. spillage into the eyes, wash immediately and liberally with water.

* The injured healthcare workers (HCW) should report to the location supervisor immediately after the injury has occurred for documentation.

* The location supervisor should refer the exposed HCW to the designated doctor immediately for risk assessment and treatment.
* The location supervisor should notify the incident to the Occupational Safety and Health Committee Secretary
* Occupational Health Unit/Infection Control Unit/ Occupational Safety and Health Committee should record the incident in the Sharps Injury Management Registry and follow up the HCW accordingly to ensure complete management of the HCW.

RISK ASSESSMENT

INJURY

- Potential to transmit HIV, HBV and HCV based on the type of body substance involved, the route and severity of the injury.
- Exposures to fluids or tissue through a percutaneous injury or through contact with mucous membrane increase risk for blood borne virus transmission and thus require further evaluation.
- Direct contact with concentrated virus in a research laboratory or production facility requires clinical evaluation.
- For skin exposure, follow-up is required only if it involves exposure to a potentially infectious body fluids if there is compromised skin integrity (e.g. dermatitis, abrasion, or open wound).
- Human bites: If a bite results in blood exposure to either of the persons involved, post exposure follow-up should be provided.

SOURCES

- Every effort should be made to ascertain the HIV, HBV and HCV status of the source.
- If the source is unknown or cannot be tested, epidemiological assessment for the likelihood of transmission of HIV, HBV, or HCV should be considered.
- Testing of the source patient must follow guidelines which includes:

1. The reasons for testing and other possible concerns which should be addressed before blood taking
2. Confidentiality of the source person should be maintained at all times.

- Testing of needles or other sharp instruments involved in an exposure, regardless of whether the source is known or unknown is not recommended.

References: Guidelines on Occupational Exposures To Human Immunodeficiency Virus (HIV), Hepatitis B Virus(HBV) and Hepatitis C Virus, and recommendations for Post Exposure Prophylaxis(PEP), 2007.

Recommended HIV Post Exposure Prophylaxis (PEP) for Percutaneous Injuries

Exposure Type	HIV Positive Class 1	HIV Positive Class 2	Source of Unknown HIV Status	Unknown Source	HIV Negative
Less Severe	Recommend basic 2-drug PEP	Recommend expanded >3-drug PEP	Generally, no PEP is warranted. Consider basic 2-drug PEP for source with HIV risk factors	Generally, no PEP is warranted. However, consider basic 2-drug PEP in settings in which exposure to HIV infected person is likely	No PEP is warranted
More Severe	Recommend expanded >3-drug PEP	Recommend expanded >3-drug PEP	Generally, no PEP is warranted. Consider basic 2-drug PEP for source with HIV risk actors	Generally, no PEP is warranted; However, consider basic 2-drug PEP in settings in which exposure to HIV infected person is likely	No PEP is warranted

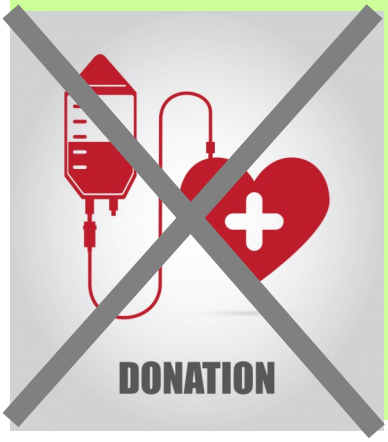
Regimen Category	Drug Regimen
Basic Regimen:	Zidovudine (AZT) 300mg BD and Lamivudine (3TC)
2 NRTI	150mg BD
	or
	2. Combivir 1 tab BD
Expanded Regimen:	Basic regimen plus Kaletra 3 tab BD for 28 days
2 NRTI + Proteus Inhibitor	If Kaletra not available:
	2. Basic regimen plus Indinavir 800mg 12 hourly with Ritonovir 100mg 12 hourly for 28 days
	or
	3. Basic regimen plus Indinavir 800mg 8 hourly

During 6 month of follow up, healthcare workers are advise to:

(a) Not to donate plasma, blood, body tissue, breast milk or sperm;

(b) To consider safe sex (e.g. use of condoms).

(c) To consult the Head of Department regarding the need to modify work practices involving EPP if he/she develops clinical or serological evidence of healthcare verosemia.



Resources: Guidelines on Occupational Exposures To Human Immunodeficiency Virus(HIV), Hepatitis B Virus(HBV) and Hepatitis C Virus, and recommendations for Post Exposure Prophylaxis (PEP), 2007.

STRATEGIES TO REDUCE POTENTIAL OCCUPATIONAL EXPOSURES

All healthcare workers should be informed, educated and trained on the following:

1. Possible risks and prevention of blood-borne infections after an occupational exposure.
2. The measures needed to prevent blood-borne pathogen exposures:

   -Implementation of standard precautions.
   -Provision of personal protective equipment and safety devices.
   -Implementation of safer procedures.

3. HBV vaccination.
4. The principles of post-exposure management and the importance of seeking immediate advice following any occupational exposure.

All health care facilities must have an efficient system for reporting and managing potential exposures of HCW to blood and other body fluids which include written protocols for prompt reporting, evaluation, counseling, treatment, and follow-up of occupational exposures.

Resources: Guidelines on Occupational Exposures To Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus, and recommendations for Post Exposure Prophylaxis (PEP), MOH Malaysia 2007.

MYCOPHENOLATE (MYCOPHENOLATE MOFETIL AND MYCOPHENOLIC ACID):

IMPORTANT NEW INFORMATION ON THE TERATOGENIC RISK

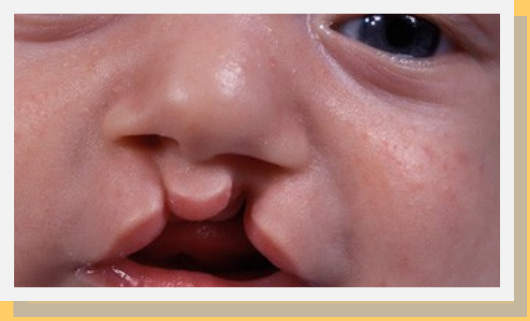
The immunosuppressant medication, mycophenolate (mycophenolate mofetil and mycophenolic acid), is known to have human teratogenic effects. A routine re-evaluation of the benefit-risk balance of medicines containing mycophenolate by the European Medicines Agency (EMA) revealed evidence of an increased rate of congenital malformations and spontaneous abortions associated with mycophenolate as compared to other medicines. Following a review of this new safety information by NPRA, the existing warnings against the use of these medicines in pregnancy have been strengthened with the addition of new contraindications and advice. A directive was issued by the Drug Control Authority (DCA) on 25 March 2016 requiring the local package inserts of all products containing mycophenolate to be updated with this new information.

Further Information on Safety Issue The review of post-marketing ADR reports and literature evidence on the teratogenic risk of mycophenolate revealed the following updated evidence:

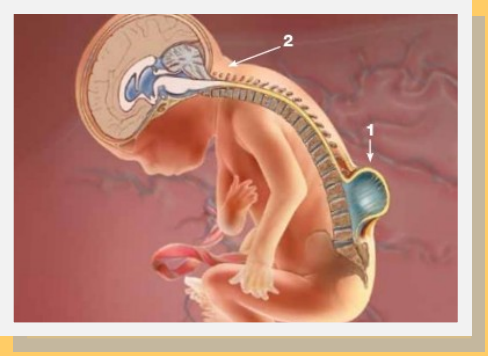
(i) spontaneous abortion in around 45-49% of pregnancies in women exposed to mycophenolate, compared with reported frequencies of 12-33% in solid organ transplant patients treated with other immunosuppressants.

Adapted from MADRAC Newsletter, April 2016.

(ii) Congenital malformations in 23-27% of the offspring of mothers exposed to mycophenolate during pregnancy, compared with 4-5% in transplant patients treated with other immunosuppressants, and 2-3% in the overall population. The most frequently reported malformations were: Facial malformations such as cleft lip, cleft palate, micrognathia and hypertelorism of the orbits; Abnormalities of the ear (e.g. abnormally formed or absent external/ middle ear) Abnormalities of the eye (e.g. coloboma, microphthalmos); Malformations of the fingers (e.g. polydactyly, syndactyly, brachydactyly); Cardiac abnormalities such as atrial and ventricular septal defects; Oesophageal malformations (e.g. oesophageal atresia); Nervous system malformations (such as spina bifida).



Cleft lip



Spina bifida

Local Scenario Products containing mycophenolate have been registered in Malaysia since 1998. Currently, there are nine (9) products registered with the DCA, seven (7) containing mycophenolate mofetil and two (2) containing mycophenolate sodium. Since year 2000, the NPRA has received 103 ADR reports with 162 adverse events suspected to be related to mycophenolate. The most frequently reported adverse event was diarrhoea, followed by leucopenia, increased hepatic enzymes, abdominal discomfort, and vomiting. As yet, the NPRA has not received any ADR reports on teratogenic effects or reports involving the use of mycophenolate in pregnancy. A Direct Healthcare Professional Communication (DHPC) related to this issue was approved by the NPRA and distributed in December 2015 to highlight the new safety information to healthcare professionals.

Adapted from MADRAC Newsletter, April 2016.

Advice to Healthcare Professionals Mycophenolate is contraindicated in pregnancy, breastfeeding, and in women of childbearing potential not using highly effective contraceptive methods. Before starting treatment with mycophenolate, women of childbearing potential must have two negative serum or urine pregnancy tests.

Counselling points:

- Before starting treatment, female and male patients of reproductive potential must be made aware of the increased risk of pregnancy loss and congenital malformations.
- All patients must be counseled regarding pregnancy prevention, and planning.
- Patients should consult their doctor immediately if they become pregnant.

Recommended contraception:

- Women of child bearing potential: Use two reliable forms of contraception simultaneously, including one highly-effective method, before starting mycophenolate therapy, during therapy, and for six weeks after discontinuation of therapy.
- Men (including vasectomised men): Use condoms during treatment and for at least 90 days after cessation of treatment. Female partners of male patients are recommended to use highly effective contraception during treatment and for 90 days after the last dose of mycophenolate.

Adapted from MADRAC Newsletter, April 2016.

Mycophenolate (CellCept) is used with other medications to help prevent transplant organ rejection (attack of the transplanted organ by the immune system of the person receiving the organ) in people who have received kidney, heart, and liver transplants. Mycophenolate (Myfortic) is used with other medications to help prevent the body from rejecting kidney transplants. Mycophenolate is in a class of medications called immunosuppressive agents. It works by weakening the body's immune system so it will not attack and reject the transplanted organ.

RESOURCES: https://medlineplus.gov/druginfo/meds/a601081.html

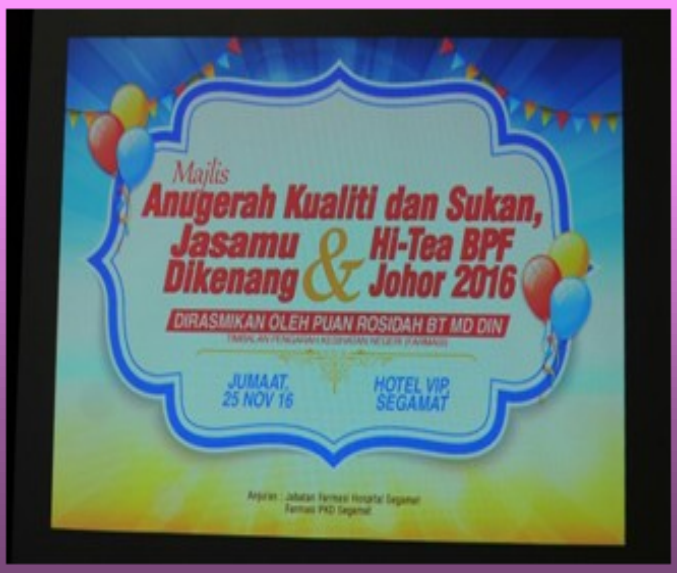
AKTIVITI JABATAN FARMASI OKTOBER - DISEMBER 2016

PHARMILY DAY 2016.

Hari Keluarga Peringkat Jabatan Farmasi tahun ini telah diadakan pada 30 September – 1 Oktober 2016 bertempat di Gambang Resort.

MAJLIS ANUGERAH KUALITI & SUKAN, JASAMU DIKENANG DAN HIGH TEA

Majlis Anugerah Kualiti & Sukan, Jasamu dikenang dan High Tea Tahunan Bahagian Perkhidmatan Farmasi Johor diadakan pada 25 November 2016 di Hotel VIP, Segamat.



Majlis ini diadakan bagi meraikan pesara-pesara sebagai tanda penghargaan kepada mereka yang telah bertungkus lumus memberikan perkhidmatan. Di samping itu, majlis Hi-Tea ini diadakan bertujuan untuk memberikan penghargaan kepada pemenang-pemenang anugerah kualiti & sukan tahunan 2016 Bahagian Perkhidmatan Farmasi Johor.

Majlis telah dihadiri tetamu kehormat iaitu Pn Hajah Rosidah bt Md Din, Timbalan Pengarah Kesihatan Negeri (Farmasi) Johor, En Ali bin Ismail, Ketua Penolong Pengarah Kanan A&P, Pn Masliza bt Arip, Ketua Penolong Pengarah Kanan (K) dan seluruh warga farmasi negeri Johor.

Majlis telah diserikan dengan jamuan makan dan beberapa persembahan yang menarik.

MAJLIS PERPISAHAN CIK CHUA ANG HOON(5 OKTOBER 2016)

Ms Chua telah berkhidmat sebagai Penolong Pegawai Farmasi selama 37 tahun. Terima kasih Kak Chua.