PHARMACY BULETIN

HOSPITAL SEGAMAT

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MELIOIDOSIS

Introduction

Melioidosis or Whitmore's disease is an infectious disease that can infect humans or animals. It is predominately a disease of tropical climates, especially in Southeast Asia and northern Australia where it is widespread. The bacteria causing melioidosis, *Burkholderia pseudomallei* are found in contaminated water and soil. It is spread to humans and animals through direct contact with the contaminated source.

Transmission

1. Direct contact with contaminated soil and water.
2. Inhalation of contaminated dust or water droplets
3. Ingestion of contaminated water
4. Ingestion of soil-contaminated food or other contact with contaminated soil, especially through skin abrasions.
5. Topical freshwater fish have also been identified as a risk of possible infection.

Signs and Symptoms

Localized Infection:
- Localized pain or swelling
- Fever
- Ulceration
- Abscess

Pulmonary Infection:
- Cough
- Chest pain
- High fever
- Headache
- Anorexia

Bloodstream Infection:
- Fever
- Headache
- Respiratory distress
- Abdominal discomfort
- Joint pain
- Disorientation

Disseminated Infection:
- Fever
- Weight loss
- Stomach or chest pain
- Muscle or joint pain
- Headache
- Central nervous system/brain infection
- Seizures

Centers for Disease Control and Prevention (Melioidosis)

Treatment (NAG 2019)

7. **MELIOIDOSIS** (*Burkholderia pseudomallei)*			
Intensive Therapy (Uncomplicated)	Ceftazidime 100-120mg/kg/24h IV q6-8h (usual dose: 2gm IV q6h)		*Add on Trimethoprim/ Sulphamethoxazole in eye, neurologic, testicular, prostatic, pericardium, bone

Infection/Condition & Likely Organism	Suggested Treatment		Comments
	Preferred	Alternative	
	PLUS/MINUS *Trimethoprim/ Sulphamethoxazole • < 40 kg: 160/800mg PO q12h • 40-60kg: 240/1200mg PO q12h • >60kg: 320/1600 mg PO q12h		and joint melioidosis. Dose as per eradication therapy. Drainage of abscesses should be attempted where ever appropriate such as prostatic, empyema and pericardium. **Duration of intensive therapy:** • Skin, bacteraemia with no foci, mild pneumonia: 2 weeks • Complicated pneumonia, prostatic, deep-seated foci, septic arthritis: 4 weeks • Osteomyelitis: 6 weeks • Neurologic/CNS: 8 weeks To use clinical judgement to guide prolongation of intensive phase if improvement is slow/persistent bacteraemia.
Intensive Therapy (Complicated) (Severe melioidosis or neuromelioidosis)	Meropenem 75mg/kg/24h IV q8h (usual dose: 1gm IV q8h; if neurologic, 2gm IV q8h) **OR** Imipenem 50mg/kg/24h IV q6h (usual dose: 500-1000mg q6h) **PLUS/MINUS** *Trimethoprim/ Sulphamethoxazole (to deescalate to Ceftazidime once symptoms improve/stable)		
Eradication/Maintenance Therapy	Trimethoprim/ Sulphamethoxazole • < 40 kg: 160/800mg PO q12h • 40-60kg: 240/1200mg PO q12h • >60kg: 320/1600 mg PO q12h	Amoxicillin/clavulanate • <60kg: 1250mg (2 tabs of 625 mg) PO q8h • >60kg: 1875mg (3 tabs of 625 mg) PO q8h	**Duration of eradication therapy:** • Osteomyelitis, Neurologic/CNS: 24 weeks • Others: minimum 12 weeks

Peadiatrics treatment dose (NAG, 2019)

Melioidosis *Burkholderia pseudomallei*			
Intensive/Induction therapy:	Ceftazidime 200mg/kg/day IV in 3 divided doses	Imipenem/cilastatin 75-100mg/kg/day IV in 4 divided doses	Duration: 2-8 weeks – Uncomplicated: 2 weeks

Infection/Condition & Likely Organism	Suggested Treatment		Comments
	Preferred	Alternative	
		OR Meropenem 75mg/kg/day IV in 3 divided doses (neurological melioidosis: 150mg/kg/day IV in 3 divided dose)	– Complicated pneumonia, deep-seated infection, neurological melioidosis, osteomyelitis & septic arthritis: 4-8 weeks
Maintenance therapy:	Trimethoprim/sulfamethoxazole 8mg/kg/day (of TMP component) PO in 2 divided doses **PLUS** Doxycycline 4mg/kg/day PO in 2 divided doses (children above 8 years old)	**Children below 8 years old:** Amoxicillin/clavulanate 20mg/kg/dose (of amoxicillin component) PO q8h (higher relapse rate)	Duration: 20 weeks Folic acid 5mg PO q24h to be given for patients on Trimethoprim/sulfamethoxazole. Consider combination therapy of two drugs in maintenance phase if high risk of relapse.

Renal dose treatment
(Melioidosis: The 2014 Revised RDH Guideline)

Appendix. Darwin melioidosis adult treatment dosing in renal impairment (The Zulfikar Jabbar Guideline[20])

	Dose adjustment by CLcr (ml/min)[a]			Dose adjustment for dialysis[b]		
	31-50	15-30	<15	HD	CAPD	CRRT
Ceftazidime	Up to 60kg 1 g q8h Over 60kg 2 g q8h	Up to 60kg 1g q12h Over 60kg 2g q12h	Up to 60kg 1 g q24h Over 60kg 2 g q24h	as for eGFR <15, dose after dialysis	as for eGFR <15 (if intravenous route inconvenient, can administer intraperitoneally with dwell time of >6 hr and 25% extra dose)	2g q12h
Meropenem	1 g q12h	1 g q12h	1 g q24h	as for eGFR <15, dose after dialysis	as for eGFR <15	1 g q8h
TMP+SMX[c]	Up to 60kg 240+1200 mg q12h Over 60kg 320+1600 mg q12h	Up to 60kg 240+1200 mg q24h Over 60kg 320+1600 mg q24h	Up to 60kg 240+1200 mg q24h Over 60kg 320+1600 mg q24h	as for eGFR <15, dose after dialysis	as for eGFR <15	as for eGFR 15-30

[a] CLcr- Creatinine clearance is calculated by Cockroft-Gault method [140-age (years) x ideal body weight) x 0.85 (female) /0.814 x serum creatinine (micromol/L) x 72)]. Recommend to use ideal body weight for weight based dose calculation

[b] HD- haemodialysis; CAPD- chronic ambulatory peritoneal dialysis; CRRT- continuous renal replacement therapy

[c] TMP+SMX: trimethoprim+sulfamethoxazole. Folic acid 5mg daily is added for the duration of therapy

OSELTAMIVIR

RISK OF HAEMORRHAGES

Overview

- Oseltamivir is indicated for the treatment and prophylaxis of influenza and is available in the form of capsules and oral suspension.

Background

The National Pharmaceutical Regulatory Agency (NPRA) has received information from Health Canada on the potential risk of haemorrhages in general with the use of oseltamivir.

Health Canada had started a safety review following an update by the Pharmaceuticals and Medical Devices Agency (PMDA), Japan, on an update of safety information for oseltamivir products with new information on the risk of haemorrhages in general. In the safety review, Health Canada had reviewed information from the Canadian Vigilance dan international database as well as published literature on the potential link between the use of oseltamivir with the risk of haemorrhages in general. Based on the review, the information was found to be inadequate. However, it was concluded that there may be a link on the use of oseltamivir and the risk of lower gastrointestinal bleeding. As the Canadian product safety information for oseltamivir has already included information on the risk of gastrointestinal bleeding, there was no further product information update required.

Adverse Drug Reaction (ADR) Reports

NPRA has received a total of 175 ADR reports with 295 adverse events suspected to be related to oseltamivir-containing products.3 There were reports of bleeding adverse events associated with oseltamivir use, such as epistaxis and petechiae but no event of gastrointestinal bleeding. Both adverse events appeared to have occurred in small children aged 9 months old and 4 years old.

Advice for Healthcare Professionals

- Be alert on the risk of haemorrhages when prescribing oseltamivir to patients.
- Advise patients and their caretakers to be practice caution whilst on oseltamivir therapy, and to inform healthcare professionals if any bleeding symptoms including epistaxis and haematemesis occurred.
- Please report all suspected adverse events associated with oseltamivir to the NPRA.

MYCOPHENOLATE MOFETIL (MMF) AND MYOCOPHENOLIC ACID (MPA): RISK OF DE NOVO PURINE SYNTHESIS INHIBITORS-ASSOCIATED ACUTE INFLAMMATORY SYNDROME

OVERVIEW

Mycophenolic acid (MPA) is an immunosuppressant that is potent, selective, non-competitive and is a reversible inhibitor of inosine monophosphate dehydrogenase (IMPDH), which is involved in the de novo pathway of guanosine nucleotide synthesis.It is indicated with corticosteroids and ciclosporin for the prophylaxis of acute transplant rejection in adult patients receiving renal transplants.

Mycophenolate mofetil (MMF), the 2-morpholinoethyl ester of mycophenolic acid (MPA), is indicated for the prophylaxis of acute organ rejection in patients receiving organ transplants such as kidney, heart and liver. It is also indicated with corticosteroids for treatment of lupus nephritis (for full prescribing details, please refer to product package insert).

Both MMF and MPA exert immunosuppressive effects which are mainly based on the inhibition of the de novo purine biosynthesis required for proliferation of T- and B-lymphocytes.

De novo purine synthesis inhibitor-associated acute inflammatory syndrome is an extremely rare paradoxical reaction which is characterised by pyrexia, arthritis, arthralgia, myalgia and elevated levels of inflammatory markers.

In Malaysia, there are currently eight (8) MMF products and four (4) MPA products registered with the Drug Control Authority (DCA). Adverse events such as arthralgia, myalgia and pyrexia have been documented as common manifestations of acute inflammatory syndrome in MMF and MPA package inserts.

BACKGROUND OF SAFETY ISSUE

The National Pharmaceutical Regulatory Agency (NPRA) has received information from European Medicines Agency (EMA) on de novo purine synthesis inhibitors-associated acute inflammatory syndrome.The signal was identified from the assessment of Periodic Safety Update Report (PSUR) for MMF and MPA-containing products. Based on reports from literature and post-marketing reports with close temporal relationship, positive dechallenge and rechallenge and plausible mechanism of action, the Pharmacovigilance Risk Assessment Committee (PRAC) of EMA considers a causal relationship between MMF, MPA and de novo purine synthesis inhibitors-associated acute inflammatory syndrome. EMA has requested the product registration holders of the products involved to update package insert with the risk of de novo purine synthesis inhibitors-associated acute inflammatory syndrome.

ADVERSE DRUG REACTION (ADR) REPORTS

NPRA has received 34 ADR reports with 59 adverse events suspected to be related to mycophenolic acid (MPA) and 134 ADR reports with 256 adverse events suspected to be related to mycophenolate mofetil (MMF). The most frequently reported adverse events for MPA were diarrhoea (7), white blood count decreased (4) and kidney transplant rejection (4), while for MMF were diarrhoea (55), vomiting (11), nausea (11) and abdominal discomfort (9). To date, no ADR report of acute inflammatory syndrome related to MPA and MMF has been received by NPRA.

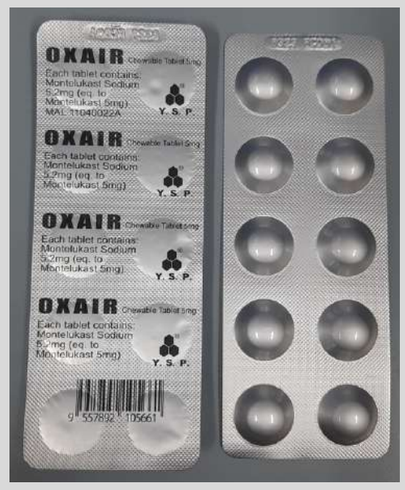
ADVICE FOR HEALTHCARE PROFESSIONALS

- Be alert on the risk of acute inflammatory syndrome following the use of MPA and MMF.
- Carefully consider this risk when patients are showing the signs and symptoms of pyrexia, arthritis, arthralgia, myalgia and elevated inflammatory markers.
- Consider discontinuation of MMF or MPA containing products as literature case reports showed rapid improvement and resolution of symptoms.
- Please report all suspected adverse events associated with MMF and MPA containing products to the NPRA.

PRODUCT BRAND CHANGES

Previous Brand	Current Brand
T. ALFUZOSIN 10MG	
 *XATRAL XL (SANOFI-AVENTIS)*	 *ALFUTOR ER (TORRENT PHARMACEUTICALS)*
T. ACETYLSALICYLIC ACID 100MG & GLYCINE 45MG	
 *GLYPRIN (DUOPHARMA)*	 *WINCARDIA (KCK PHARMACEUTICALS)*
C. CELECOXIB 200MG	
 **CELEBREX (PFIZER PHARMACEUTICALS LLC)**	 **HOVID- CELECOXIB CAP (HOVID BHD)**
T. HYDROXYCHLOROQUINE 200MG	
 **UNIQUIN (UNIMED)**	 **PLAQUENIL (SANOFI)**

PRODUCT BRAND CHANGES

Previous Brand	Current Brand
T. MONTELUKAST 5MG	
	
AIRLUKAST (RANBAXY)	***OXAIR (YSP)***
T. QUETIAPINE IR 100MG	
	
APO-QUETIAPINE (APOTEX)	***QUTERO (HETERO)***
T. TELMISARTAN 40MG	
	
TOLURA-40 (KRKA)	***TELEACT (RANBAXY)***
OFLOXACIN 0.3% OTIC SOLUTION	
	
TARIVID (DAICHI SANKYO)	***EFFEXIN (KOONG KOREA)***

Dapsone-induced Methaemoglobinaemia

Case Report

A 28-year-old male patient with newly diagnosed retroviral disease and previous history of co-trimoxazole allergy was given oral dapsone 100 mg daily for the prophylaxis of Pneumocystis carinii pneumonia (PCP). Two (2) days after the initiation of dapsone, he developed
multiple spikes of fever and dry cough. On investigation, his temperature was 38.9°C and SpO2 87-90% in room air.
He was well-perfused with warm peripheries but had dusky appearance with bluish nails. The patient remained cyanosed despite receiving oxygen supplementation via nasal prong. His arterial blood gas showed increased methaemoglobin level at 10.4% (normal range: 1-3%).
The patient was diagnosed with dapsone-induced methaemoglobinaemia. The drug was withdrawn and the patient received supportive treatment with oxygen and activated charcoal. Three (3) days after the diagnosis, the patient achieved full recovery with methaemoglobinaemia level normalised to 1.2%

Advice to Healthcare Professionals

- Be aware on the possible association between dapsone use and methemoglobinemia.
- Consider the possibility of methaemoglobinaemia in patients receiving dapsone who have presented with cyanosis and decreased saturation levels on pulse oximetry. Further investigations such as arterial blood gas analysis and methaemoglobin level may be required to confirm the diagnosis and severity of the adverse event.
- Educate patients on the symptoms of methaemoglobinema and advise patients to immediately seek a doctor if signs and symptoms of methaemoglobinemia developed.
- Initial management of methaemoglobinaemia includes discontinuation of the offending drug and provision of supportive care. Treatment with methylene blue intravenously at 1 to 2 mg/kg of body weight over 5 minutes can be given to patients who are symptomatic or with a methaemoglobin level of 30% and above. In patients who do not respond to treatment with methylene blue alone, activated charcoal, exchange transfusions and hyperbaric oxygen therapy may be considered.
- Report any ADRs suspected to be related to the use of dapsone to NPRA.

Discussion

Dapsone is a synthetic sulfone that is used as an antimicrobial agent in treating leprosy, mycetoma, toxoplasmosis and in the prophylaxis of malaria. It exerts its bacteriostatic effect by interfering with folate synthesis, an essential step in the production of DNA in bacterial cell division. Dapsone is also used as an anti-inflammatory agent in other medical conditions, such as dermatitis herpetiformis and other dermatoses. Although the exact mechanism of action has not been fully elucidated, the anti-inflammatory action of dapsone is thought to be associated with decreasing neutrophil migration to the lesion site and the moderation of the level of damage by neutrophils when treating inflammatory conditions. In Malaysia, there is currently one registered product containing dapsone.

Methaemoglobinaemia is a known adverse event induced by dapsone. Metabolites of dapsone are potent oxidants that may trigger the conversion of ferrous [Fe2+] ion in the haemoglobin to its oxidised ferric [Fe3+] state. The adverse event itself is a potentially life-threatening condition, as the oxidation of Fe2+ reduces the oxygen carrying capacity of the haemoglobin, leading to decreased oxygen delivery to the body tissues, resulting in hypoxia. The severity of the presenting signs and symptoms of methaemoglobinaemia is related to the levels of methaemoglobin in blood.

NPRA has received 232 adverse drug reaction (ADR) reports with 431 adverse events associated with dapsone use. Some of the common adverse events reported include skin reactions such as rash (90), pruritus (32) and drug reaction with eosinophilia and systemic symptoms (DRESS) (28). Currently, there are 12 ADR reports of methaemoglobinaemia associated with the use of dapsone (including the case report discussed above).
As of March 2021, a search in the World Health Organisation (WHO) global ADR database revealed a total of 486 reports of methaemoglobinaemia, 106 reports of cyanosis, and eight reports of tachypnoea, suspected to be associated with dapsone.

Reference

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CLOZAPINE-INDUCED GASTROINTESTINAL HYPOMOTILITY (CIGH)

Case Report 1

A 51-year-old female patient was taking tablet clozapine 125 mg twice daily and later increased to 125 mg OM and 250 mg ON for resistant schizophrenia. She has been on treatment for the past 9 years. She was reported to experience constipation, which subsequently escalated to colitis and ileus paralytic. Clozapine was suspected and withdrawn from treatment, and the patient was reported to be recovering from the adverse reaction.

Case Report 2

A male patient of an unknown age was started on tablet clozapine 150 mg twice daily for resistant schizophrenia. The patient was reported to have developed intestinal obstruction associated with perforated viscus after 15 days of treatment. The patient was reported to have died due to that and it was unknown whether or not an autopsy was performed.

Clozapine is an atypical antipsychotic, derived from the tricyclic dibenzodiazepine family. It possesses weak dopamine receptor-blocking activity at D1, D2, D3 and D5 receptors, but shows high potency for the D4 receptor, in addition to potent anti-alpha-adrenergic, anticholinergic, antihistaminic and sedative properties. Clozapine has also been shown to have antiserotonergic properties. It is the drug of choice to treat resistant schizophrenia in patients who are intolerant or non-responsive to classical neuroleptics. It has desirable outcomes in terms of improvement in mental health, quality of life and life expectancy.

Gastrointestinal hypomotility is a condition of reduced contraction forces of the gut smooth muscles or prolonged transit time in the gastrointestinal tract. It may be genetic in nature, acquired from extrinsic factors (e.g. sedentary lifestyle, overweight, a lacking in fluids and fibre intake) or induced by drugs. These contributing factors render the CIGH to be under detected and under-reported.

A patient with gastrointestinal hypomotility may not only present with a variety of symptoms, but may also have compromised nutritional absorption and bowel output. It may develop to other gastrointestinal complications such as dyspepsia, gastroparesis, chronic constipation, irritable bowel syndrome (IBS), or more severely, intestinal pseudoobstruction or ileus.

Clozapine is commonly associated to a spectrum of gastrointestinal adverse events that has been attributed to clozapine-induced gastrointestinal hypomotility (CIGH),ranging from constipation to faecal impaction, intestinal obstruction and paralytic ileus. Previous studies show clozapine delays colon transit, mostly due to its anticholinergicand antiserotonergic properties. CIGH may be potentially life-threatening, and is associated with a high mortality rate

.

In a 22-year retrospective pharmacovigilance study in Australia and New Zealand to investigate serious or fatal CIGH, the analysis identified 160 out of 43,132 subjects receiving clozapine were associated with serious CIGH, where 29 subjects (18%) have died from CIGH. The reported prevalence of serious CIGH was estimated to be 37 in 10,000 clozapine users, but it is thought that this figure is an underestimation of the true prevalence.

A result from a study on the effects of clozapine in the gut by adopting a wireless motility capsule technology, showed that 82% of the subjects prescribed with clozapine (n = 17) were found to experience reduced bowel motility in at least one region of the gastrointestinal tract - stomach, small intestine or colon. While 59% of the subjects experienced multiregional gastrointestinal dysmotility, half of the subjects experienced delayed colon transit (50%), others were diagnosed with delayed small bowel transit (71%) and delayed gastric emptying (41%).

In Malaysia, there are currently seven registered products containing clozapine. NPRA has received 333 adverse drug reaction (ADR) reports with 571 adverse events related to clozapine. Adverse events related to CIGH include constipation (27), intestinal obstruction (9), abdominal pain (6), ileus paralytic (6), abdominal distension (4), and gastrointestinal hypomotility (3) and chronic constipation (2). From the World Health Organisation (WHO) global ADR database, there were 170,891 cases reported adverse reactions linked to clozapine. A total of 4,694 cases were CIGH-related adverse reactions such as constipation (3,134), intestinal obstruction (1,002), ileus (543), ileus paralytic (360) and gastrointestinal hypomotility (76).

In January 2020, the United States Food and Drug Administration (US FDA) has issued a drug safety communication on the risk of serious bowel complications associated with clozapine, and a new warning on this risk is required to be updated in the prescribing information of clozapine products. This requirement was concluded following a safety review on the FDA Adverse Event Reporting System (FAERS) Database. In the 10-year review (2006 – 2016), there were 10 cases describing constipation that later progressed to serious gastrointestinal complications, resulting in hospitalisation, the need for surgery, or death.

The National Pharmaceutical Regulatory Agency (NPRA) has completed a safety review on the risk of serious bowel complications caused by constipation associated with clozapine. A safety alert on this risk has been communicated to healthcare professionals and a directive [Ref. No.: NPRA.600-1/9/13 (13)] has been released in the NPRA website for product registration holders to add new warnings and updates on this risk in the clozapine package inserts as well as consumer medication information leaflets (Risalah Maklumat Ubat untuk Pengguna).

Advice to Healthcare Professionals

- ***Assess the patient's bowel habit before initiating clozapine. Remind patients and their caretakers to monitor on the frequency and quality of their bowel movements throughout clozapine treatment.***
- ***Use lowest effective clozapine dose and avoid co-prescribing clozapine with other drugs that may induce constipation or gastrointestinal hypomotility (e.g. opiates, anticholinergic drugs).***
- ***In high-risk patients and patients with previous history of chronic constipation or bowel obstruction, consider the use of laxatives as a prophylaxis during clozapine therapy.***
- ***Inform patients and their caretakers to see a doctor if they are having symptoms of reduced bowel movement such as (e.g. low stool frequency, lack of urge to defecate, hard or dry stools, difficulty passing gas, nausea, bloating, abdominal pain, and vomiting).***
- ***Advise patients and their caretakers not to stop taking clozapine without first talking to the doctor, as stopping treatment may trigger symptoms of schizophrenia or cause relapse.***
- ***Educate patients and their caretakers on the importance of high fibre dietary intake such as fruits, vegetables and grains, as well as maintaining good hydration and daily physical activity to prevent constipation.***
- ***Report all ADRs suspected to be related to clozapine to NPRA.***

pharmacy activities

july-sept

Pada 16 Ogos 2021, Kursus Tatacara Pengurusan Stor telah dianjurkan bertempat di Dewan Perdana, Hospital Segamat bermula daripada jam 8 pagi hingga 5 petang. Kursus yang melibatkan 50 orang peserta ini dijalankan bertujuan untuk memberi pengetahuan tentang pengurusan stor yang baik bagi memastikan stor dapat diuruskan secara teratur. Selain itu, untuk memastikan proses-proses penerimaan, pengeluaran serta penyimpanan stok dilaksanakan mengikut Tatacara Pengurusan Stor.

Kursus Keselamatan Pengubatan Bil 2/2021 telah dijalankan pada 22 September 2021 jam 8 pagi hingga 12 tengahari bertujuan untuk menggariskan aspek keselamatan pesakit yang perlu diberi keutamaan oleh semua anggota penjagaan kesihatan dalam memastikan pesakit mendapat ubat yang betul pada dos yang betul pada masa pengambilan yang betul melalui cara pengambilan yang betul. Seramai 22 orang peserta telah menghadiri kursus ini yang dijalankan di Dewan Perdana, Hospital Segamat.

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DRUG INFORMATION & ENQUIRIES ON MEDICATION

DRUG INFORMATION CENTRE HOSPITAL SEGAMAT CAN BE REACHED AT 07-9433333 (EXT.141) DURING OFFICE HOURS (MON TO FRI, 8.00AM TO 5.00PM)