PHARMACY BULLETIN

BIL 1/2020 (JANUARY – APRIL)

JABATAN FARMASI HOSPITAL TENGKU AMPUAN AFZAN, KUANTAN, PAHANG

IN THIS ISSUE:

SPECIAL TOPIC:

NDMA IMPURITES

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HTAA PHARMACY STAFF UPDATES 2020

TRANSFERRED IN

ARYANI BINTI AHMAD

PEGAWAI FARMASI UF54

DATE OF TRANSFER: 13/01/2020

FROM: JKNP

TO: FARMASI MAKMUR

SOH SHEN-NI

PEGAWAI FARMASI UF52

DATE OF TRANSFER: 03/02/2020

FROM: KK KURNIA

TO: PRIC

TOU PUI YEE

PEGAWAI FARMASI UF52

DATE OF TRANSFER: 20/01/2020

FROM: KK BANDAR KUANTAN

TO: FARMASI BEKALAN WAD

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TRANSFERRED IN

CHIEW SIOW YEH

PEGAWAI FARMASI UF48

DATE OF TRANSFER: 13/01/2020

FROM: PKD KEPONG

TO: FARMASI KLINIK PAKAR

EMY LEE POOI VERN

PEGAWAI FARMASI UF48

DATE OF TRANSFER: 03/02/2020

FROM: JKN PAHANG

TO: FARMASI KLINIK PAKAR

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PEGAWAI FARMASI UF48

DATE OF TRANSFER: 10/02/2020

FROM: KK BALOK

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PEGAWAI FARMASI UF44

DATE OF TRANSFER: 06/01/2020

FROM: HOSPITAL KUNAK, SABAH

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FAAIEZATUL HUSNA BINTI BAKAR

PEGAWAI FARMASI UF41 (KONTRAK)

DATE OF TRANSFER: 03/02/2020

FROM: HSNZ

TO: FARMASI KLINIK PAKAR

ZURINA BINTI MAT YUNUS

PENOLONG PEGAWAI FARMASI U32

DATE OF TRANSFER: 06/01/2020

FROM: KK AYER KEROH, MELAKA

TO: FARMASI BEKALAN WAD

HTAA PHARMACY STAFF UPDATES 2020

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ROHAYA BINTI SULAIMAN @ JAMALUDDIN

PEGAWAI FARMASI UF54

DATE OF TRANSFER: 03/02/2020

TO: KK BANDAR KUANTAN

NIK ZAHERAN MAT YASIN

PEGAWAI FARMASI UF54

DATE OF TRANSFER: 06/01/2020

TO: KK BANDAR KUANTAN

NOR HAFIZAH BINTI SALEHUDIN

PEGAWAI FARMASI UF54

DATE OF TRANSFER: 06/01/2020

TO: KK BANDAR BERA 32

HTAA PHARMACY STAFF UPDATES 2020

TRANSFERRED OUT

YEOH MEI CHIN

PEGAWAI FARMASI UF52

DATE OF TRANSFER: 06/01/2020

TO: KK JAYA GADING

TANG WOAN TORNG

PEGAWAI FARMASI UF48

DATE OF TRANSFER: 06/01/2020

TO: HOSPITAL KUALA LUMPUR

RABIATUL ADAWIAH BINTI NAZRI

PEGAWAI FARMASI UF48

DATE OF TRANSFER: 09/03/2020

TO: HOSPITAL MANJUNG

HTAA PHARMACY STAFF UPDATES 2020

TRANSFERRED OUT

YEE WEN WEI

PEGAWAI FARMASI UF44

DATE OF TRANSFER: 06/01/2020

TO: JKWPKL

LIEW ZHI HSIUNG

PEGAWAI FARMASI UF44

DATE OF TRANSFER: 02/03/2020

TO: PKD SEBERANG PERAI TENGAH

RABWAN BINTI MUDA

PENOLONG PEGAWAI FARMASI U36

DATE OF TRANSFER: 06/01/2020

TO: KK BESERAH

HTAA PHARMACY STAFF UPDATES 2020

TRANSFERRED OUT

ROHAYU BINTI PUTEH

PEMBANTU TADBIR N22

DATE OF TRANSFER: 20/01/2020

TO: HOSPITAL PEKAN

HTAA INTERNAL RESHUFFLE

MUHAMMAD MARZUKI BIN SHAMSUDIN

PEMBANTU PERAWATAN KESIHATAN U11

TO: DAYCARE

DATE OF RESHUFFLE: 13/01/2020

HTAA PHARMACY STAFF UPDATES 2020

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PEGAWAI FARMASI UF41 (KONTRAK)

DATE OF RESIGNATION: 01/01/2020

NURNAZURAH BINTI FAISAL

PEGAWAI FARMASI UF41 (KONTRAK)

DATE OF RESIGNATION: 18/01/2020

N-NITROSODIMETHYLAMINE (NDMA) IMPURITIES

By Nurul Huda Mohammad Fakhruddin

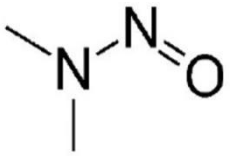


Figure 1: *N*- nitrosodimethylamine (NDMA)

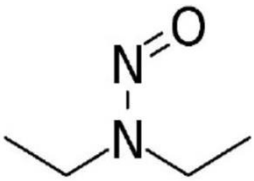


Figure 2: *N*-nitrosodiethylamine (NDEA)

Chronology of NDMA Detection in Ranitidine (Zantac) Products in Malaysia

On September 2019, European Medicines Agency reviewed ranitidine medicines following detection of NDMA

↓

FDA Statement – alerting patients & Health Care Professionals of NDMA found in samples of ranitidine

↓

Reassessment of 20 registered Ranitidine products by National Pharmaceutical Regulatory Agency (NPRA)

↓

Sampling and testing & Evaluation and reports

↓

3 products below NDMA interim limit 0.32ppm. 17 products exceed the limit. Affected batches were recalled from market

What are Nitrosamines?

Nitrosamines, or more correctly **N-nitrosoamines**, refer to any molecules containing the nitroso functional group (Figure 1 & 2). NDMA belongs to the so-called 'cohort of concern', which is a group of highly potent mutagenic carcinogens that have been classified by the WHO's International Agency for Research on Cancer as probable human carcinogens. Long term exposure above certain levels may increase the risk of cancer. They are found to be present in low level in processed food, i.e. pickled vegetables, salted fish, processed meat products and the environment, i.e. air pollution.

Why are they present?

The formation of nitrosamines are generally only possible when secondary or tertiary amines react with nitrous acid. Nitrous acid itself is unstable but can be formed in situ from nitrites (NO2) under acidic conditions. However, the origins of NDMA content in batches of ranitidine currently remains unclear.

Primary Sources of Human Exposure to NDMA

Human can be exposed to NDMA through diet. Food such as processed meat such as sausages, cheese and beer are known sources of NDMA. A study by Herrmann et al. (2014) showed that 50% of the analyzed processed meat samples obtained from a Danish market contain NDMA, with 4mcg/kg being the highest value seen in the study.

Identified Sources of Nitrosamine in Pharmaceutical Products

- Use of sodium nitrite (NaNO2) or other nitrosating agents, in the presence of secondary and tertiary amines.
- Use of contaminated raw materials (eg. solvents, reagents, catalysts) starting materials and intermediates, recovered material.
- Cross-contaminations
- Degradation processes of starting materials, intermediates and drug substances.
- Use of certain packaging materials

Interim Limits for N-Nitrosamine Impurities

Impurity name Abbreviation	Chemical Name	Allowable Daily Intake (AI)*
NDMA	**N-nitrosodimethylamine**	**96.0 ng/day**
NDEA	N- nitrosodiethylamine	26.5 ng/day
NMBA	N-nitroso-N-methyl-4-aminobutyric acid	96.0 ng/day
DIPNA	N-nitrosodiisopropylamine	26.5 ng/day
EIPNA	N-nitrosoethylisopropylamine	26.5 ng/day

**The allowable daily intake (AI) is a daily exposure to a compound such as NDMA, NDEA or NMBA that approximates a 1:100,000 cancer risk after 70 years exposure (max. daily dose) – US FDA*

Despite the potency of these impurities, there is still a very low risk that nitrosamine impurities at the levels found could cause cancer in humans. In a study conducted among 5150 Danish patients taking NDMA-contaminated Valsartan, there was no obvious increase of short-term overall risk of cancer in these patients. However, studies with longer follow-up are needed to assess long term cancer risk (Pottegard et al., 2018).

Genotoxic substances such as NDMA may increase the risk of cancer if people are exposed to them above acceptable levels and over long periods of time, **but a person taking a drug that contains NDMA at/below the acceptable daily intake limit every day for 70 years is not expected to have an increased risk of cancer. -US FDA**

References:

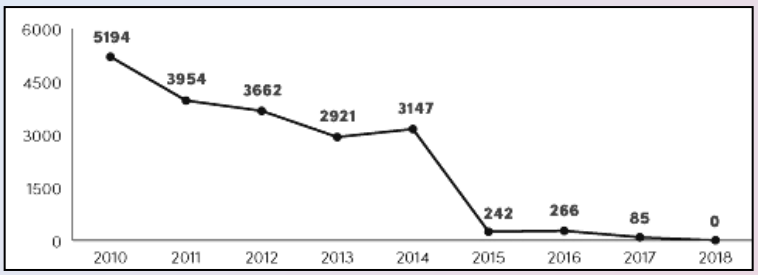
1. World health organization. (2019). WHO Information Note: Update on Nitrosamine Impurities. Switzerland.
2. Mitch et al.. (2003). N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review. Environmental Engineering Science, 20(5), 389-404.
3. Pottegard et al., (2018). Use of N-nitrosodimethylamine (NDMA) contaminated valsartan products and risk of cancer: Danish nationwide cohort study. *BMJ*, 362(1), 1-7.
4. N-Nitrosodimethylamine - Agency for Toxic Substances and Disease Registry
5. Herrmann et al., (2014). Simultaneous determination of volatile and non-volatile nitrosamines in processed meat products by liquid chromatography tandem mass spectrometry using atmospheric pressure chemical ionisation and electrospray ionisation. *Journal of Chromatography A*, 1330 (1), 20-29.

MALARIA Disease and management

By : Amirah Binti Mohammad

In 2018, Malaysia has reported 499 cases (imported and introduced from other countries) of the human-to-human type of malaria, and 4,131 cases of zoonotic malaria (macaque to human or Plasmodium knowlesi infection in Malaysia.

However, in reaching zero indigenous human malaria cases in 2018 as targeted by National Strategic Plan for the Elimination of Malaria , Malaysia has accomplished its goal 2 years ahead of schedule based on WHO report 2018.

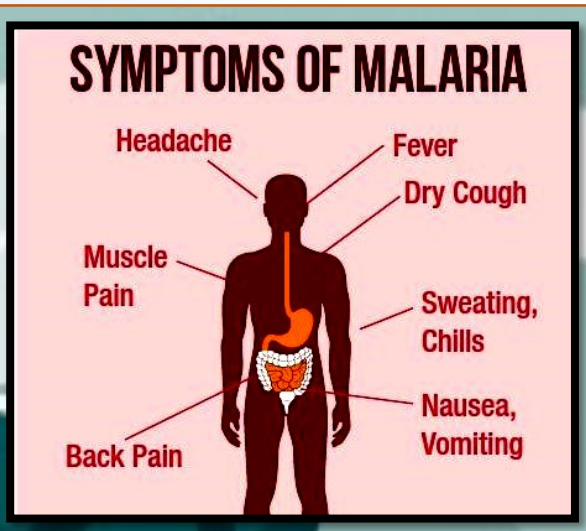


*Number of **indigenuous malaria cases** in Malaysia.*
Source : E-2020 malaria report WHO

Under Communicable Diseases Control Act 1988, malaria is listed as notifiable disease which needs to be notified within 7 days, but to ensure early investigations and sufficient measures, practitioners need to notify it to nearest health office within 24 hours.

WHO 2019 Progress Report of Malaria in Malaysia

- **0** indigenous malaria cases in 2018 *(acquired by mosquito transmission in common malaria area)*
- **21** introduced malaria cases in 2018 (*acquired from an imported case in an area where malaria is uncommon)*
- **485** imported malaria cases in 2018 *(acquired outside a specific area)*
- **12** malaria death in 2018



Malaria parasites.

Malaria is caused by infection of red blood cells with protozoan parasites of the genus *Plasmodium*, single-celled organisms that cannot survive outside of their host(s). It infects human through a feeding female *Anopheles* mosquito. There are 5 different types plasmodium species which are *P.Falciparum*, *P. Malariae, P. Vivas, P. Ovale* and *P. Knowlesi*. Among the forementioned parasites, 2 of these species – *P. falciparum* and *P. vivax* pose the greatest threat.

In Malaysia, dominant malaria species are *P. vivax* and *P. knowlesi*. High risk populations include labourers in agriculture, farming and forestry sector as well as aboriginal groups of East Malaysia

Clinical features

Malaria is an acute febrile illness. In a non-immune individual, symptoms usually appear 10–15 days after the infective mosquito bite. The first symptoms fever, headache, and chills may be mild and difficult to recognize as malaria. If not treated within 24 hours, *P. falciparum* malaria can progress to severe illness, often leading to death.

Clinical features appear due to toxic factors released by parasites infecting the red blood cells. When the infected red cells lyse, it stimulates macrophages and other cells to produce cytokines and other soluble factors which act to produce fever and rigors

Incubation period varies among different species, where In more than 90% *P. Falciparum* cases, symptoms occur within 6 weeks of the traveler leaving an endemic area, while for *P. Vivax*, the symptoms may occur in 1 year. For *P. Knowlesi* which usually related to forested or forest-tinge area, symptoms may occur in 9-12 days.

Reference

1. *E-2020 initiative of 21 malaria-eliminating countries 2019 progress report, World Health Organization (WHO)*
2. National Antibiotic Guideline 2014, Ministry of Health Malaysia.
3. Clinical Practice Guideline of Malaria 2013, Ministry of Health Malaysia.
3. Retrieved from https://www.cdc.gov/malaria/about/disease.html

TREATMENTS

Condition & Likely Organism	Preferred	Alternative	Comments
P. falciparum a(i) Non Complicated - New Infection	**Riamet® (1 tablet: Artemether/ lumefantrine 20/120mg)** The patient should receive an initial dose, followed by 2nd dose 8 hours later, then 1 dose q12h for the following 2 days	**Artesunate /Mefloquine** 5 - 8kg : 25/55mg PO q24h 9 - 17kg : 50/110mg PO q24h 18 - 29kg: 100/220mg PO q24h ≥30kg : 200/440mg PO q24h for 3 days OR Quinine 10mg/kg PO q8h PLUS Doxycycline 100mg PO q12h for 7 days OR Quinine 10mg/kg PO q8h PLUS ł Clindamycin 600mg PO q12h for 7	**Artesunate /Mefloquine** available as FDC tablet: **25/55mg** and **100/220mg** Primaquine 0.75mg/kg (max: 45mg) to be given on Day 1 as a single dose except in pregnant/lactating woman (check G6PD status before use)
P. falciparum a(ii) Non Complicated - Treatment failure or relapse	If Riamet® is used as the first line regimen, so the choice will be Artesunate /Mefloquine and vice versa)	**Quinine** 10mg/kg PO q8h PLUS **Doxycycline** 100mg PO q12h for 7 days	Mefloquine should not be repeated within 60 days of first treatment due to increased risk of neuropsychiatric side effects.
P. falciparum b) Complicated *	**Artesunate** 2.4mg/kg IV at 0 hour, 12 hour, 24 hour and q24h till day 7* PLUS/MINUS Doxycycline 100mg PO q12h for 7 days	**Loading dose Quinine** 20mg/kg IV over 4 hours in D5% on day 1, then Quinine 10mg/kg IV/PO q8h **PLUS Doxycycline** 100mg PO q12h for 7 days OR Quinine 7mg/kg IV over 1 hour, followed by 10mg/kg in D5% over 4 hours on day 1, then Quinine 10mg/kg IV/PO q8h PLUS Doxycycline 100mg PO q12h for 7 days	*Parenteral artesunate should be given for a minimum of 24 hours (3 doses) or until patient can tolerate orally then it can be switched to a complete course of oral ACT regime
* Features of severe/complicated Malaria includes ≥1 features: Impaired consciousness or unrousable coma, Prostration (generalized weakness so that the patient is unable to walk or sit up without assistance), Failure to feed/ not tolerating orally, Convulsion, Deep breathing, respiratory distress (acidotic breathing), Circulatory collapse or shock			
P. vivax/ovale a) New infection	**Chloroquine** 10mg/kg (max 600mg) PO stat, then 5mg/kg (max 300mg) 6 hours later, followed by q24h for 2 days **PLUS Primaquine** 0.5mg/kg (max 30mg) PO q24h for 14 days		G6PD deficiency: Primaquine 0.75mg/kg PO q7d for 8 weeks. If significant haemolysis occurs, should be stopped.
P. vivax/ovale b) Treatment failure or suspected chloroquine resistance	**RIAMET** (dose as above) PLUS **Primaquine** 0.5mg/kg (max 30mg) PO q24h for 14 days		If severe *P.vivax,* treatment is as complicated *P.Falciparum.*
P. malariae/ knowlesi	**Riamet®** (dosing as per *P. falciparum*	**Artesunate /Mefloquine** (dosing as per *P. falciparum* treatment) OR Chloroquine 10mg/kg (max 600mg) PO stat, then 5mg/kg (max 300mg) 6 hours later, followed by q24h for 2 days	If severe *P.malariae/knowlesi*, treatment is as complicated *P.Falciparum.*

Source : Clinical Practice Guideline Malaria 2013, Ministry of Healh Malaysia

BELL'S PALSY

Prepared by: NUR SHAHANIM BINTI SABRI

What is Bell's Palsy?

Bell's palsy, named after Scottish anatomist, Sir Charles Bell, presents of rapid unilateral facial nerve paresis (weakness) or paralysis (complete loss of movement) of unknown cause. The condition leads to the partial or complete inability to voluntarily move facial muscles on the affected side of the face.

When evaluating a patient with facial weakness/paralysis for Bell's palsy, the following should be considered:

- Bell's palsy is rapid in onset (<72hours).
- Bell's palsy is diagnosed when no other medical etiology is identified as a cause of the facial weakness.
- Bell's palsy is common in patients with diabetes, upper respiratory ailments, or compromised immune systems; or during pregnancy
- Bell's palsy is typically self-limiting.

The House-Brackmann Facial Nerve Grading Scale is one of the most commonly used tools for the clinical evaluation of facial nerve function as shown in Table 1.

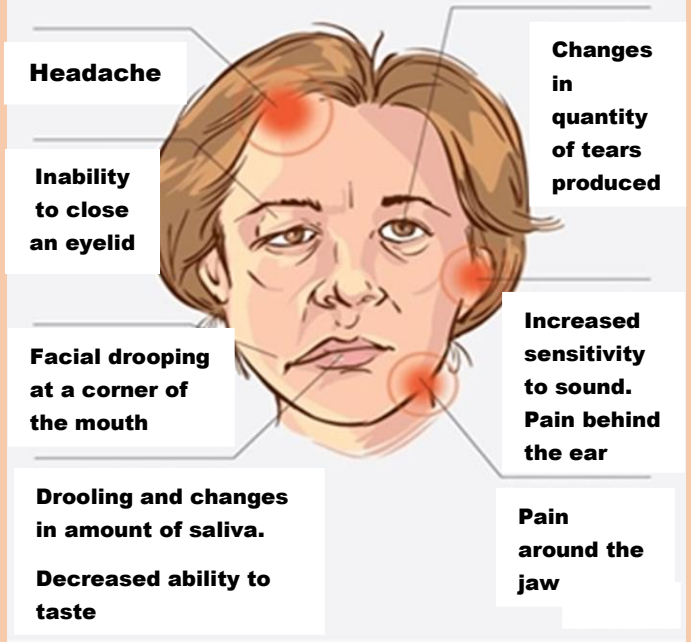
This scale is used to determine the severity of facial nerve dysfunction in people with facial palsy.

Table 1: House- Brackmann Facial Nerve Grading System

Grade	Description	Characteristics
I	Normal	Normal facial function in all areas
II	Mild dysfunction	Slight weakness noticeable on close inspection; may have very slight synkinesis
III	Moderate dysfunction	Obvious, but not disfiguring, difference between 2 sides; noticeable, but not severe, synkinesis, contracture, or hemifacial spasm; complete eye closure with effort
IV	Moderately severe dysfunction	Obvious weakness or disfiguring asymmetry; normal symmetry and tone at rest; incomplete eye closure
V	Severe dysfunction	Only barely perceptible motion; asymmetry at rest
VI	Total paralysis	No movement

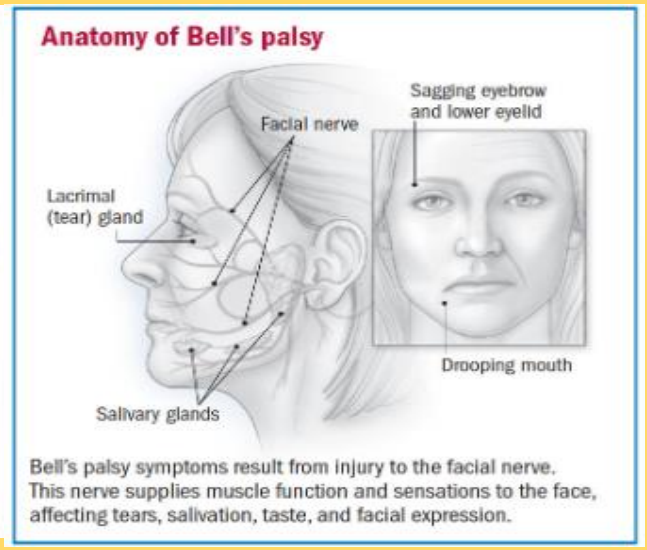
(Canadian Medical Association Journal, 2014)

SIGNS & SYMPTOMS

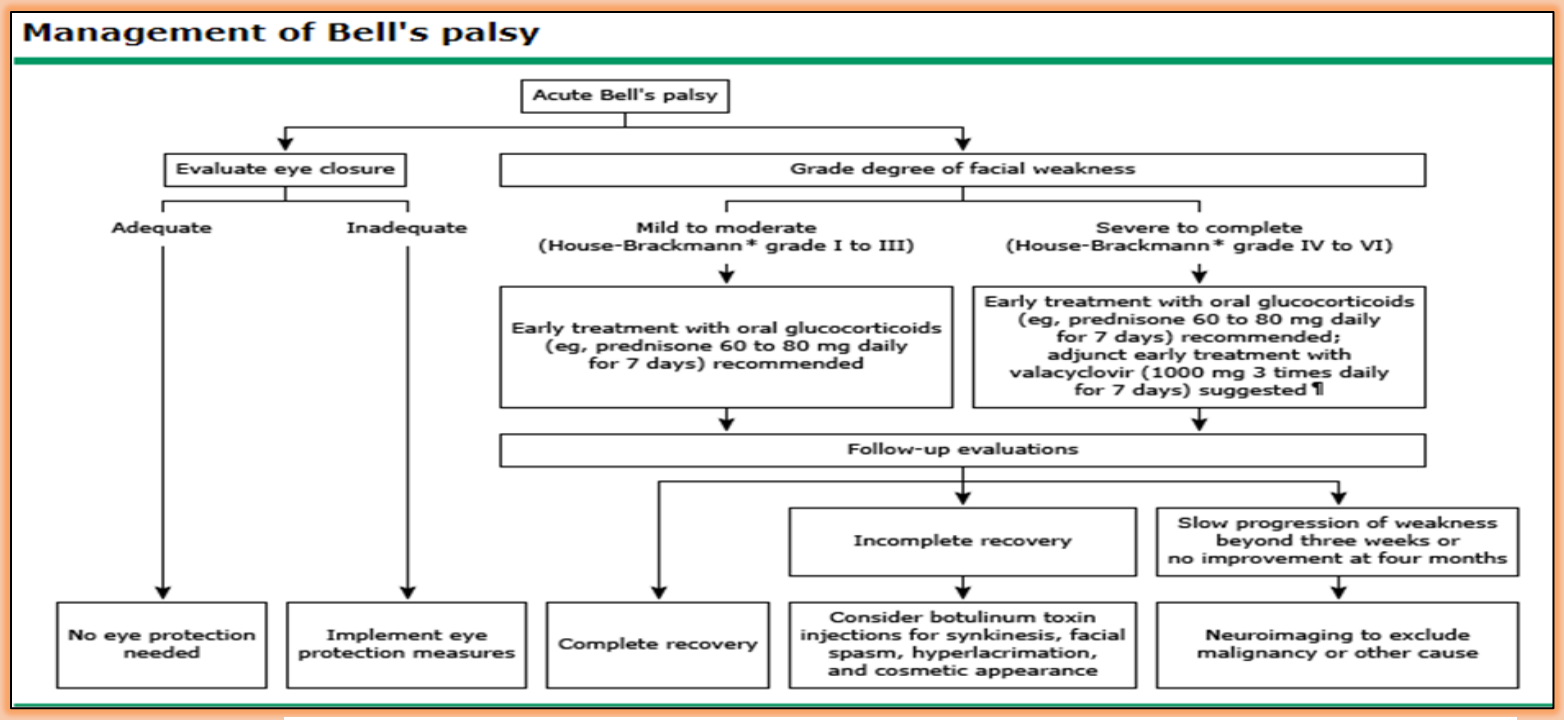


How does it occur?

While a viral etiology is suspected, the exact mechanism of Bell's palsy is currently unknown. Facial paresis or paralysis is thought to result from facial nerve inflammation and edema. The facial nerve carries nerve impulses to muscles of the face, and also to the lacrimal glands, salivary glands, stapedius muscle, taste fibers from the anterior tongue, and general sensory fibers from the tympanic membrane. As the facial nerve travels in a narrow canal within the temporal bone, swelling may lead to nerve compression and result in temporary or permanent nerve damage.



Bell's palsy symptoms result from injury to the facial nerve. This nerve supplies muscle function and sensations to the face, affecting tears, salivation, taste, and facial expression.



Adapted from: de Almeida JR, Guyatt GH, Sud S, et al. Management of Bell palsy: clinical practice guideline. CMAJ 2014; 186:917.

PHARMACOLOGICAL THERAPY

PREDNISOLONE

1)The rationale for the use of corticosteroids in acute phase of Bell's palsy is that inflammation and edema of the facial nerve are implicated in causing Bell's palsy, and corticosteroids have a potent anti-inflammatory action which should minimise nerve damage and thereby improve the outcome.

2)Prednisolone should be used in all patients with facial palsy within 72h from the onset of symptoms.

3) The suggested prednisolone dose is 60 to 80mg daily for 5-7 days: administered in 1 or 2 divided doses; may be followed by a 5-day taper.

ANTIVIRAL AGENTS

1)Evaluation of the use of antiviral medicines in Bell palsy has shown limited benefit from these drugs.

2)However, given the evidence suggesting that a large percentage of Bell palsy cases may result from a viral infection, the use of antiviral agents such as valacyclovir or acyclovir may be reasonable in certain situations.

3) Acyclovir is administered at a dosage of 400 mg orally 5 times daily for 10 days. Evidence supports Herpes Simplex Virus (HSV) as a major cause of Bell palsy. If Varicella Zoster Virus (VZV) is suspected, higher doses may be needed (800 mg orally 5 times daily).

LOCAL MANAGEMENT OF BELL'S PALSY THERAPY

EYE CARE

1) A common short-term complication of Bell's palsy is incomplete eyelid closure with resultant dry eye. Artificial tears should be applied every hour while the patient is awake, and ointment formulations should be used at night.

2) In severe cases of Bell's palsy, the cornea may be at risk because of poor eyelid closure and reduced tearing. This may result in corneal drying and abrasion, with an associated risk of visual loss.

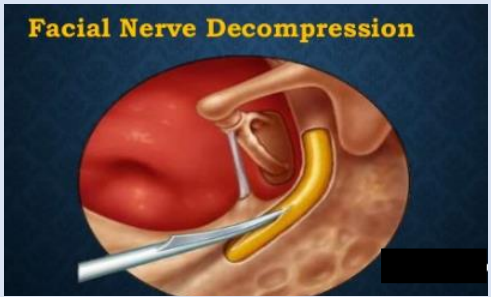
BOTULINUM TOXIN INJECTION

1) Botulinum toxin injection may help in relaxing the facial muscles after they have developed mass contraction, though the results are not as satisfying in patients with Bell's palsy as in patients with idiopathic hemifacial spasm.

SURGICAL DECOMPRESSION

1)An uncontrolled study suggested that decompression may be of benefit in patients with profound facial nerve dysfunction.

2) However, it should not be undertaken if facial paralysis has been present for 14 or more days, since severe degeneration of the facial nerve is probably irreversible after two to three weeks.



References:

1)Clinical Practice Guideline Summary : Bell's Palsy- AAO-HNS Bulletin, November 2013, pg 35-37.

2) De Almeida, John R et al. "Management of Bell palsy: clinical practice guideline." CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne vol. 186,12 (2014): 917-22. doi:10.1503/cmaj.131801

3) Retrieved from https://dentagama.com/news/bells-palsy-unilateral-facial-paralysis

4) UpToDate

DRUG UPDATES

Inj. Aflibercept 40mg/mL (EYLEA)

A. DESCRIPTION

- EYLEA, 40 mg / mL solution for intravitreal injection contains 40 mg aflibercept.
- Aflibercept is fusion protein consisting of portions of human VEGF (Vascular Endothelial Growth Factor) receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and produced in Chinese hamster ovary (CHO) K1 cells by recombinant DNA technology.
- Each single-dose, pre-filled syringe provides a usable amount to deliver a single dose of 50 microliters containing 2 mg aflibercept

B. REGISTRATION NUMBER

MAL13035065AZ

C. PRICE

RM 2230/vial

D. DEPARTMENT

Ophthalmology

E. PREGNANCY CATEGORY

Category C

F. PRESCRIBER CATEGORY

A*

(Consultant/ Specialists for specific indications only)

G. MECHANISM OF ACTION

- Aflibercept is a recombinant fusion protein that acts as a decoy receptor for vascular endothelial growth factor-A (VEGF-A) and placental growth factor (P_LGF).
- Aflibercept binds to VEGF-A and P_LGF and inhibits binding and activating of endothelial cell receptors, thereby suppressingneovascularization and slowing vision loss.

H. INDICATION

i Treatment of neovascular (wet) age-related macular degeneration (wet AMD).

ii Visual impairment due to diabetic macular edema (DME). Prescribing restriction:
   a) Treatment of naive patients with visual acuity equal or worse than 20/50; or
   b) Patients with poor response to treatment with ranibizumab.

I. DOSE AND ADMINISTRATION

i The recommended dose is 2mg aflibercept, equivalent to 0.05mL (50 µL) given as intra-vitreal injection. Aflibercept treatment is initiated with one injection per month for three consecutive doses, followed by one injection every two months.

ii 2 mg aflibercept (equivalent to 50 microliters) administered by intravitreal injection monthly for the first 5 consecutive doses, followed by one injection every 2 months. There is no requirement for monitoring between injections.

DRUG UPDATES

J. ADVERSE EFFECT

Common Adverse Reaction

- Conjunctiva Haemorrhage
- cataract
- Eye pain

Others

- Cardiovascular: Arterial thrombosis
- Central nervous system: Foreign body sensation
- Immunologic:Antibody development
- Local: Pain at injection site, bleeding at injection site
- Ophthalmic: Increased intraocular pressure, vitreous detachment,vitreous opacity,epithelial keratopathy, ocular hyperemia

K. WARNING AND PRECAUTIONS

Concerns related to adverse effects:

- Endophthalmitis/retinal detachment: Intravitreous injections are associated with endophthalmitis, retinal detachments, retinal tear, retinal pigment epithelium tear, and cataract, including traumatic cataract.
- Hypersensitivity reactions:

  Increased intraocular pressure: Following intravitreal injection, intraocular pressure may increase (acute). Onset is seen within 60 minutes. Sustained increases in intraocular pressure have also been reported (with repeated dosing of intravitreal VEGF inhibitors). Monitor intraocular pressure and optic nerve head perfusion

Prepared by: UMMI SALWANI BINTI ABDULLAH

L. CONTRAINDICATIONS

- Ocular or periocular infection
- Active severe intraocular inflammation
- Known hypersensitivity to aflibercept or to any of the excipients

M. USE IN SPECIAL POPULATION

- Patients with hepatic and/or renal impairment:
  - No specific studies in patients with hepatic and/or renal impairment have been conducted with EYLEA. Available data do not suggest a need for a dose adjustment with EYLEA in these patients.
- Paediatric:
  - There is no relevant use of Eylea in the paediatricpopulation in the indication wet AMD, CRVO, BRVO, DME and myopic CNV.
- Elderly:
  - No special considerations are needed for dosing

N. MONITORING PARAMETER

- Intraocular pressure immediately following injection; signs of infection/inflammation (for first week following injection)
- Optic nerve head perfusion; signs/symptoms of endophthalmitis or retinal detachment; visual acuity; signs/symptoms of hypersensitivity reaction

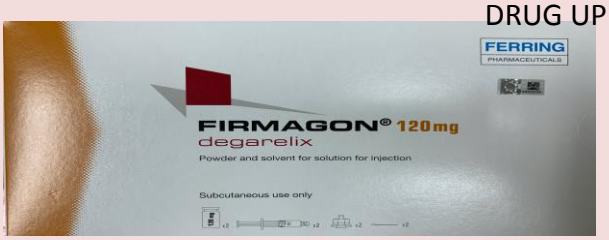
O. STORAGE

Store in a refrigerator (2°C to 8°C / 36°F to 46 °F). **Do not freeze!**

P. REFERENCES

Product leaflet, FUKKM, Micromedex, Mimsgateway, NPRA, UP-TO-DATE

DRUG UPDATES
INJECTION DEGARELIX (FIRMAGON)



A. DESCRIPTION

FIRMAGON®is a gonadotropin releasing hormone (GnRH) antagonist for advanced prostate cancer treatment of adult male patient.

Therapeutic effect should be monitored by clinical parameters and prostate specific antigen (PSA) serum levels.

B. REGISTRATION NO.

MAL13055075ARZ

C. PRICE

RM 860.50 (120mg)/pack

RM 465.60 (80mg)/pack

D. DEPARTMENT

UROLOGY

E. PRESCRIBER CATEGORY

A*

(Consultant/ Specialists for specific indications only)

F. PREGNANCY CATEGORY

Category X

G. MECHANISM OF ACTION

Degarelix is a gonadotropin releasing hormone (GnRH) receptor antagonist that binds reversibly to the pituitary GnRH receptors which results in the reduction in the release of gonadotropins including testosterone.[1].

H. INDICATION IN FUKKM

Treatment of adult male patients with advanced hormone- dependent prostate cancer Prescribing restriction: Patients who are contraindicated to Gonadotrophin Releasing Hormone (GnRH) agonist.[2].

I. DOSE AND ADMINISTRATION

Dose: 240mg administered as two consecutive subcutaneous injection of 120mg each. Maintenance dose-monthly administration: 80mg administered as one subcutaneous injection (first maintenance dose should be given one month after the starting dose).[2].

Firmagon® is for subcutaneous use only, not to be administered intraveneously. Intramuscular administration is not recommended, and it has not been studie. Firmagon® must be reconstituted prior administration Add 4.2 or 3 mL of sterile water for injection to a vial containing 80 or 120 mg, respectively, to provide a 20 or 40 mg/mL solution, respectively. Swirl gently, do not shake.[3].

J. ADVERSE REACTIONS

- Significant:

Anaemia, hypersensitivity reactions, QT prolongation, decreased BMD, decreased glucose tolerance, CV disease, antibody formation.

- Gastrointestinal disorders: Nausea, constipation, diarrhoea.
- General disorders and administration site conditions: Chills, fatigue, pyrexia, influenza-like illness injection site reactions (eg: erythema, pain), asthenia, night sweats
- Investigations: Increased hepatic transaminases.
- Metabolism and nutrition disorders: Increased weight.
- Musculoskeletal and connective tissue disorders: Back pain, arthralgia
- Nervous system disorder: Dizziness, headache.
- Psychiatric disorders: Insomnia.
- Reproductive system and breast disorders: Gynaecomastia, erectile dysfunction, testicular atrophy.
- Skin and subcutaneous tissue disorders: Rash, hyperhidrosis.
- Vascular disorders: Hot flush, hypertension.

Potentially Fatal: Rarely, anaphylaxis.

K. WARNING AND PRECAUTION

- Patient with congenital long QT syndrome, history of or risk factors for QT prolongation (e.g. cardiac failure, electrolyte imbalance)
- CV disease; diabetes, risk factors for low BMD. Moderate to severe renal (CrCl<50 mL/min) and severe hepatic impairment

Prepared by: NUR AFIQAH AMIR AZHAR

L. CONTRAINDICATION

- Hypersensitivity to any of itsingredients.
- Pregnant women or women of childbearing potential

M. USE IN SPECIFIC POPULATIONS

Renal Impairment

- Dose adjustment in patients with mild or moderate renal impairment is not recommended.
- Data on patients with severe renal impairment is scarce and caution is therefore warranted in this patient population

Hepatic impairment

- No signs of increased exposure in the hepatically impaired subjects were observed compared to healthy subjects.
- Dose adjustment is not necessary in patients with mild or moderate hepatic impairment.
- Patients with severe hepatic dysfunction have not been studied and caution is therefore warranted in this group.

N. MONITORING PARAMETERS

Monitor prostate-specific antigen (PSA), serum testosterone levels, LFTs, serum electrolytes (e.g. Na, K, Ca, Mg), BMD, ECG.

O. SHELF LIFE AND STORAGE

- Shelf life: 3 years. After reconstitution: Chemical and physical in-use stability has been demonstrated for 2 hours at 25ºC.
- Storage: below 30°C. Do not freeze

N. REFERENCES

Micromedex[1], FUKKM[2],Drug leaflet[3]

PHARMACY R&D 1

TITLE: Inappropriate Medication Prescribing for Elderly Ambulatory Care Patients based on Beers Criteria in HTAA

Author: Quah Joo Ean[1], Thilaga Manogaran[1], Umira Syahirah Shirinal Izuan[1], Nurul Ili Izyan Omar[1], Geethaavacini Gobi Raja[1], Maivizhi Selvi Mv.Rajendram[1]

[1]Department of Pharmacy, Hospital Tengku Ampuan Afzan, Kuantan.

Background: Potentially inappropriate medications (PIMs) should be avoided by the elderly because they possess a significant high risk for this population when a safer alternative is available. Inappropriate prescribing is a serious and common global healthcare problem especially in elderly people, which leads to increasing risk of adverse drug reactions (ADRs). The main risk factor contributing to both inappropriate prescribing and adverse drug reaction will be the multidiscipline prescribing which leads to poly-pharmacy. This study is aimed to identify the prevalence of inappropriate medication prescription among the elderly from ambulatory care in Hospital Tengku Ampuan Afzan (HTAA).

Objectives: To find out the incidence of PIM use in elderly in ambulatory care based on Beer's criteria, identify the drug class that is often prescribed for elderly based on Beers criteria and identify the category of prescriber who prescribes the drugs listed in Beer's criteria in HTAA.

Method: A retrospective study was carried out among elderly subjects (age ≥ 65 years) who were issued prescriptions in the outpatients department of HTAA. Data were obtained on demographics, category of prescriber and potentially inappropriate medications prescribed based Beer's criteria. Data were collected using geriatric patient prescriptions at outpatient department in HTAA from March 2016 to February 2017.

Results: (56.7%) out of 4055 geriatric patients were prescribed with PIMs as determined by Beers criteria. First-generation of antihistamines were the leading ones (32.1%), followed by Non-cyclooxygenase-selective NSAIDs (17.62%), Metochlopramide (11.53%), Ticlopidine (11.48%) and skeletal muscle relaxants (5.65%). 60.29% of the prescriptions were prescribed by Medical Officers (MO), followed by Housemen (28.36%) and the least by Specialists (11.35%).

Conclusion: The high incidence of PIMs in our study may be due to lack of awareness among healthcare providers, Hence, training of the healthcare providers about the existence of a list of inappropriate medications for the elderly population will aid to improve the rational drug use in elderly patients.

PHARMACY R&D 2

TITLE: Drug Prescribing Pattern in the Outpatient Emergency Department

Author: Yeoh Mei Chin[1], Yeoh Mei Ting[1], Lian Ming Lee[1], Nur Baizurah Mohd Ali[1], Yee Wen Wei[1], Chan Chien Shih[1], Voon Hui Shun[1], Zainatul Fadhilah Zulkarnain[1]

[1]Department of Pharmacy, Hospital Tengku Ampuan Afzan, Kuantan.

Background: Drug utilization study (DUS) forms the basis for the rationality of drug use by determining drug prescribing pattern and adherence to local formularies. A number of DUS were carried out in Malaysia but none in Outpatient Emergency Department (OED).

Objective: To describe the prescribing pattern according to the World Health Organization (WHO) drug use indicators and to study the prescribing pattern before and after the implementation of OEDL.

Method: This was a prospective study on OED prescriptions (n=360) at Hospital Tengku Ampuan Afzan, a tertiary care hospital in Kuantan, Pahang. Prescriptions were evaluatedat two times phases: before and after the implementation ofoutpatient emergency drug list (OEDL). Prescribing patternwere described according to the World Health Organization (WHO)drug use indicators, namely: **i)** average number of drugs prescribed per patient encounter, **ii)** percentage of encounters with an antibiotic prescribed, **iii)** percentage of drugs prescribed by generic name, and iv) percentage of encounters with drugs not listed in OEDL.

Results: The average number of drugs prescribed per patient was 2.51±1.41 and 2.71±1.18 for phase 1 and phase 2 respectively. The most commonly prescribed class of drugs for both Phase 1 and 2 were analgesics (18.89%) and antipyretics (17.77%); followed by antipyretics (18.22%) and analgesics (13.22%); followed by anti-infectives (14.44%) and gastro-intestinal tract (GIT) drugs (13.22%) respectively. Cloxacillin capsules was the most frequently prescribed antibiotics (N1=1152, N2=1740, Total=2892), followed by Amoxycillin capsules (N1=585, N2=1489, Total=2074) and Cefuroxime tablets (N1=692, N=254, Total=946). The percentage of antibiotic use decrease by a statistically significant 8.34% from 32.78% to 24.44% after OEDL implementation.

Conclusion: Anti-infectives were among the top three most frequently prescribed medications to patients. Rational use of antibiotics, especially broad spectrum antibiotics can be partly achieved through careful screening against OEDL to mitigate antibiotic resistance. The results of the present study are attempts to highlight the role of OEDL in optimizing medication use in OED.

PHARMACY R&D 3

TITLE: Survey on Intervention of Inpatient Prescription in Satellite Pharmacy

Author: Khairul Naim bin Zainal Abidin[1], Nurfaizza Sainal[1], Sarah Farhana Ahmad Kamil[1], Ain Farahanim Maisarah Mokhtar[1]

[1]Department of Pharmacy, Hospital Tengku Ampuan Afzan, Kuantan.

Background: Complete prescription includes elements such as generic name of the drug complete with dose, administration route, frequency, duration of treatments, patient's information such as patient's name, ward/bed number and prescriber's signature (MOH, 2010).Prescription error is a type of medication error which is defined as error occurs in prescribing decision or prescription writing process, when there is an unintentional significant reduction in the probability of treatment being timely and effective or an increase in the risk of harm when compared with generally accepted practice (Steve. C et. al, 2012).

Objectives: To determine the most common types of prescribing error that occurred in prescription received and screened by pharmacist at Satellite Pharmacy in HTAA and to determine the occurrence of intervention done by the pharmacist due to the prescription error.

Method: The study design was a prospective cross-sectional study that collected information about types of prescribing error that occurred and to identify which elements in the prescription that causing prescribing error such as patient detail (name, age, registration number) and drug detail (name, dose, frequency, route of administration).The targeted populations were all prescription for patient admitted in ward 7A, 7B, 7C, 8A, 8B and 8C which is medical wards located at 7th and 8th floor of HTAA.

Results: A total of 1600 prescription received and screened by Satellite Pharmacy during June till December 2017. Among these, around 19% from total prescription required intervention by the pharmacists. In this study, incomplete prescription (40.7%) was the most common type of prescribing error. Incomplete frequency (32.3%) would be the most common types of incomplete prescription happen in Satellite Pharmacy, followed by patient's registration number and doctor's signs and stamps (25.8% and 16.9% respectively).Beside incomplete prescription, incorrect dose (25.6%) was the second common type of prescribing errors, followed by incorrect frequency (19.7%).

Conclusion: The most common reason of incomplete prescription is due to incomplete information or missing information of patient details (name, age, registration number) and drug details (dose and frequency).

MAJLIS SAMBUTAN TAHUN BARU CINA & HARI LAHIR JAN-APR

Tarikh:
12/2/2020
Tempat:
Perkarangan UFL
Penganjur:
PharmCare

Persediaan upacara perasmian & 'Yee Sang Toss' oleh Pengarah HTAA

Antara staf yang hadir bagi memeriahkan majlis

Acara memotong kek oleh staf kelahiran Jan-Apr

Ketua Jabatan Farmasi dan Ketua Unit bergambar bersama sebagai kenangan

MAJLIS PERPISAHAN PN ROHAYA, CIK NORHAFIZAH & PN YEOH MEI CHIN

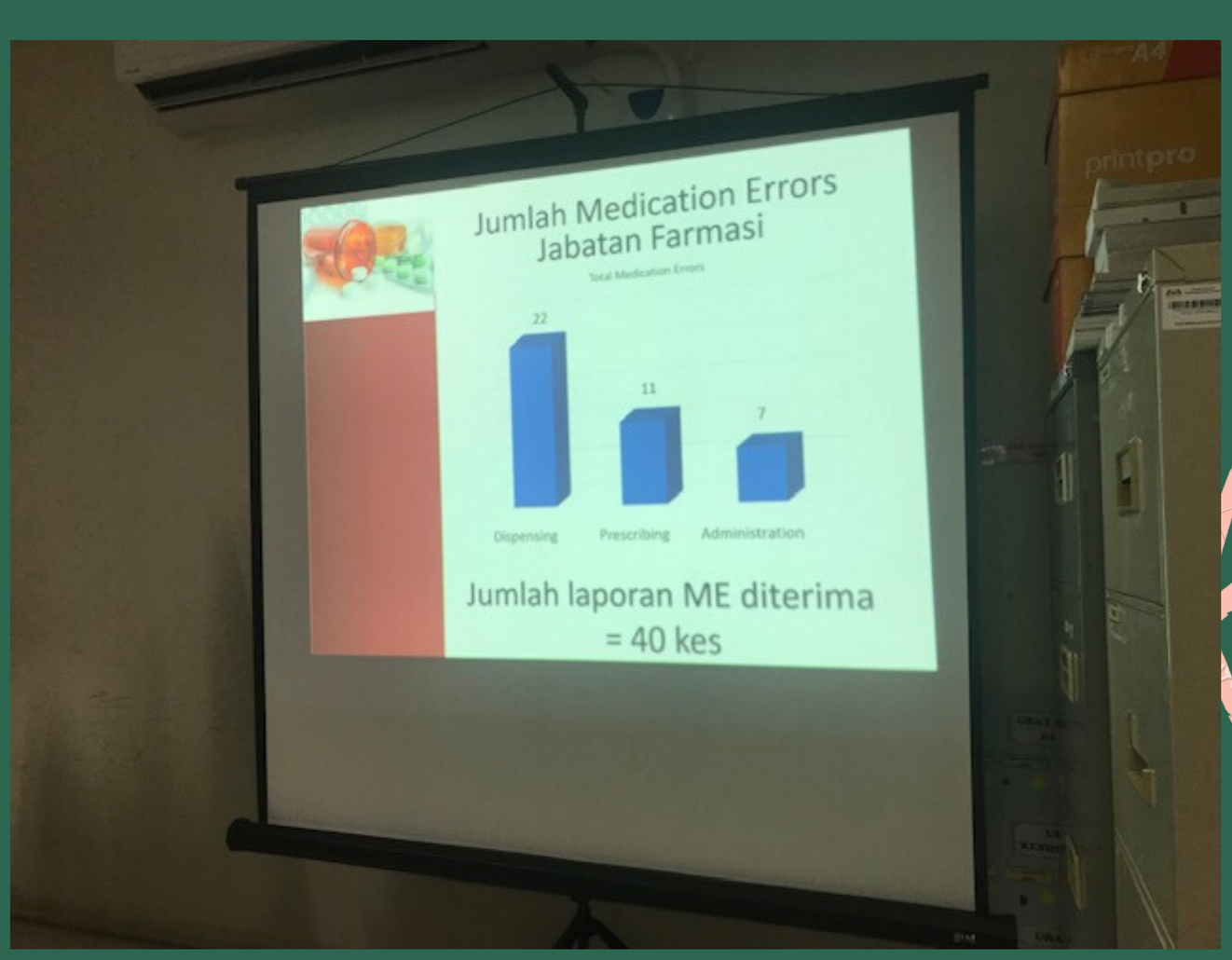
TARIKH: 15/2/2020
TEMPAT: HOTEL MEGAVIEW
PENGANJUR: PHARMCARE

KETUA JABATAN FARMASI MENYAMPAIKAN CENDERAHATI KEPADA STAF YANG BERPINDAH

MEDICATION ERROR AND ROOT CAUSE ANALYSIS

TARIKH: 19/2/2020
TEMPAT: PRIC

Puan Siti Aisyah Binti Mohamad Yusuf memberi taklimat kepada staf farmasi mengenai *medication error*



Antara staf farmasi yang hadir untuk mendengar taklimat yang diberikan