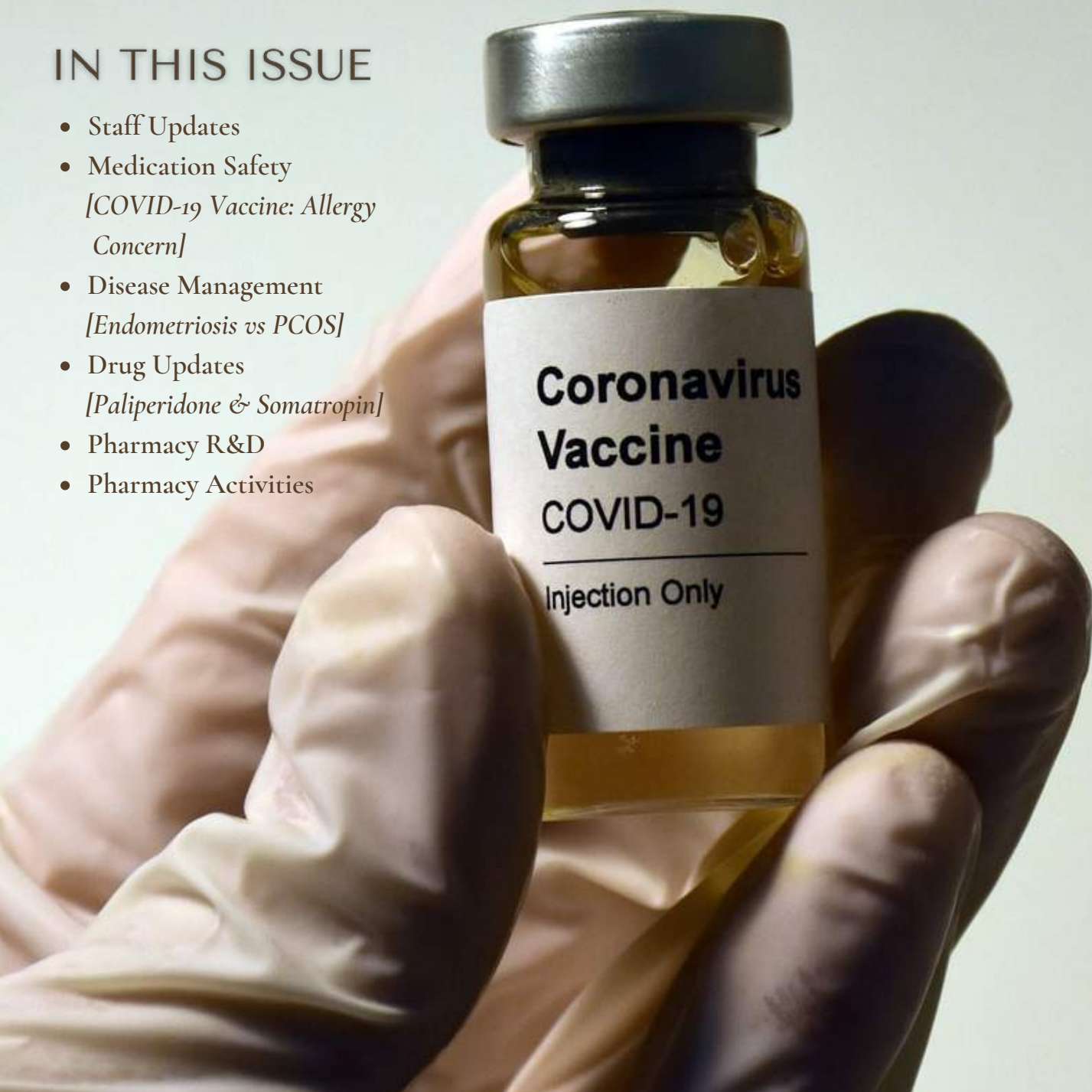


## Special Topic

# COVID-19 VACCINE: ALLERGY CONCERN

## IN THIS ISSUE

- Staff Updates
- Medication Safety  
*[COVID-19 Vaccine: Allergy Concern]*
- Disease Management  
*[Endometriosis vs PCOS]*
- Drug Updates  
*[Paliperidone & Somatropin]*
- Pharmacy R&D
- Pharmacy Activities



**ADVISOR** Hajah Samehah Almuna bt Haji Ismail

**EDITORS** Soh Shen-ni • Siti Sarah bt Ilias • Fareha bt Abdul Ghani • Siti Aisyah bt Mohd Yusof • Nor Akma Idayu bt Mohd Yusoff

## CONTRIBUTORS

Amanda Ng Yuin Shan • Darlia Syafika bt Darusalam • Nurul Wajihah bt Muhammad Zaki • Carissa Lee Xin Jin • Nurul Syafira bt Arif • Nurashikin bt Sumari • Nurfatihah bt Huzaimi

# HTAA PHARMACY STAFF UPDATES 2021

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**Pegawai Farmasi UF54**  
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**To: Farmasi Pengeluaran**

**Date Reported Duty: 29 November 2021**



**Pegawai Farmasi UF48**  
**CHOO YAI WEN**

**From: Hospital Kuala Lipis**  
**To: Farmasi Bekalan Wad**

**Date Reported Duty: 1 November 2021**



**Pegawai Farmasi UF44**  
**REBECCA CHIANG**  
**SIEW FERN**

**From: KK Paya Besar**  
**To: Farmasi Logistik**

**Date Reported Duty: 9 September 2021**



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To: Farmasi Klinik Pakar**

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**To: Farmasi Bekalan Wad**

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**Pegawai Farmasi UF41**

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**Date Reported Duty: 1 September 2021**

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Pegawai Farmasi UF54

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JKN Pahang

Date Transferred Out: 17 October 2021



Pegawai Farmasi UF54

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To: KK Indera Mahkota

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Pegawai Farmasi UF52

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SALLEH**

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Pegawai Farmasi UF48

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MAY LY**

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To: KK Bandar Kuantan

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Pegawai Farmasi UF48

**NOR SALMIAH BINTI  
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From: Farmasi Bekalan Wad

To: Hospital Sultanah Aminah, Johor Bahru

Date Transferred Out: 13 September 2021



Pegawai Farmasi UF41

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ZAINI TEE**

From: Farmasi Klinik Pakar

To: KK Tanglin, WP Kuala Lumpur

Date Transferred Out: 13 September 2021

# HTAA PHARMACY STAFF UPDATES 2021

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## [→] RESIGNED



Pegawai Farmasi UF44

**NAJIHAH BINTI CHE SEMAN**

From: Farmasi Bekalan Wad

Resigned on: 1 November 2021





# HTAA PHARMACY STAFF UPDATES 2021

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## ↻ INTERNAL RESHUFFLE



**Pembantu Awam H11**

**NOORIAH BINTI SAID**

**From: Unit Perkhidmatan Awam**

**To: Farmasi Klinik Pakar**

**Date Reported Duty: 6 September 2021**



# HTAA PHARMACY STAFF UPDATES 2021



## NEWLY APPOINTED



Pegawai Farmasi UF41 (K)

**FONG SWIIT XIN**

To: Farmasi Makmur

Date Reported Duty: 8 November 2021



Pegawai Farmasi UF41 (K)

**IMMIRATUL SAADIAH BINTI  
MOHD SAAD**

To: Farmasi Bekalan Wad

Date Reported Duty: 8 November 2021

# COVID-19 Vaccines: Allergy Concern

by: Wajihah Zaki

COVID-19 stands for "coronavirus disease 2019", caused by a virus called SARS-CoV-2. At the end of 2019, this novel coronavirus was first identified in Wuhan, a city in the Hubei Province of China, as it caused a cluster of pneumonia cases. This cluster rapidly spread, resulting in an epidemic throughout China, followed by an increasing number of cases in other countries throughout the world. In March 2020, the World Health Organization (WHO) declared COVID-19 as a global pandemic.<sup>1</sup> Ever since the emergence of this novel coronavirus, scientists have worked hard to develop COVID-19 vaccines in effort to prevent serious illness and death from COVID-19. The goal is to achieve "herd immunity", when enough people are vaccinated that the disease can no longer spread easily.<sup>2</sup>

## Allergic Reaction

One of the issues related to vaccination is an allergy. Allergy occurs when an individual reacts to substances that are usually harmless to other people.<sup>4</sup> Allergic reactions involve the immune system and may vary between individuals, ranging from mild to severe.<sup>5</sup> Allergy symptoms include sneezing, a runny or blocked nose, red, itchy, watery eyes, wheezing and coughing, a red, itchy rash, worsening of asthma or eczema symptoms. Most allergic reactions are mild, but occasionally a severe reaction called anaphylaxis or anaphylactic shock can occur. This is a medical emergency and requires urgent treatment.<sup>5</sup> Reactions that does not involve the immune system are known as adverse reactions, not allergies. As for COVID-19 vaccines, the allergens of concern that may cause allergic reactions include polyethylene glycol (PEG) and polysorbate-80, both of which are structurally related.

## Polyethylene Glycol (PEG)

PEGs are widely used as excipients in conjugated pharmaceuticals, cosmetic, industrial and food products.<sup>6</sup> Its usage extends from household to perioperative setting. They are common constituents of a variety of products including wound dressings, PEGylated drugs, hydrogels, as well as tablets, lubricants such as echocardiogram or ultrasound gel, laxatives, bowel preparations and dental floss.<sup>6</sup> PEG allergy is very uncommon despite its widespread use.<sup>6</sup> Most reported reactions to PEG in literature are due to high molecular weight PEGs.<sup>6</sup>

## Vaccine Availability Updates<sup>3</sup> :

Currently there are 7 COVID-19 vaccines approved by National Pharmaceutical Regulatory Agency (NPRA) in Malaysia which are:

- **PfizerBioNTech (Comirnaty®)**
- Moderna Biotech (Spikevax®)
- **Sinovac (CoronaVac®)**
- Sinopharm (COVIL0®)
- **OxfordAstraZeneca (ChAdOx1-S® [recombinant])**
- Janssen (Ad26.COVS-S® [Recombinant])
- **CanSinoBio (Convidecia®)**

\*vaccines in bold are those available in Pahang





Polysorbate-80

Polysorbate-80 is also an excipient in a multitude of medical preparations (e.g, vitamin oils, vaccines, and anticancer agents), creams, ointments, lotions, and tablets.<sup>6</sup> People with PEG allergy may also be allergic to polysorbate-80 which is widely used in medicines particularly in biologics, as well as processed food.<sup>6</sup> Table 1 below shows the presence of PEG and polysorbate-80 in COVID-19 vaccines available in Malaysia. <sup>6</sup>

Table 1: Presence of PEG and polysorbate-80 in COVID-19 vaccines available in Malaysia.

Type	COVID-19 vaccine	PEG	Polysorbate-80
mRNA	Cominarty® (Pfizer-BioNTech)	✓	X
	Spikevax® (Moderna)		
Adenovirus-vectored	ChAdOx1-S® (Oxford-AstraZeneca)	X	✓
	Ad26.COV2-S® [Recombinant] (Janssen)		
	Convidecia™ (CanSinoBio)		
Inactivated	CoronaVac® (Sinovac)	X	X
	COVIL0® (Sinopharm)		

Pre-Vaccination Assessment and Post-Vaccination Monitoring

At vaccination administration centres, pre-vaccination assessment is done so those with history of allergies can be properly monitored after receiving the vaccine. Post vaccination, individuals with history of allergies will be monitored on site for at least 30 minutes, as compared to 15 minutes, for other individuals.<sup>6</sup>

Case Scenarios for Allergy Assessment BEFORE the First Dose of COVID-19 Vaccine <sup>6</sup>

Allergy details	Vaccination decision	Precaution
20 years old, male with history of lip swelling and wheals after eating shellfish (prawn and crab). His symptoms resolved spontaneously within 24 hours.	This is allergy or intolerance to seafood  <b>Patient can receive COVID-19 vaccine.</b>	Observe for 30 minutes after vaccination
43 years old, female with generalized rash after flu vaccine last year. No throat swelling, no shortness of breath, no angioedema, no syncopal attack.	<b>Patient cannot receive vaccine with PEG or polysorbate as she was allergic to previous influenza vaccine. Most influenza vaccines contain polysorbate.</b>	To administer CoronaVac® (Sinovac) or COVIL0® (Sinopharm) Observe for 30 minutes after vaccination
50 years old, male with urticaria, lip swelling and shortness of breath (SOB) to penicillin 30 years ago.	Patient developed anaphylaxis to penicillin  <b>Patient can receive COVID-19 vaccine.</b>	Observe for 30 minutes after vaccination

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# Endometriosis vs. Polycystic Ovary Syndrome

By Carissa Lee Xin Jin & Nurul Syafira bt Arif

Endometriosis and polycystic ovarian syndrome (PCOS) are two separate gynecologic disorders that could significantly reduce the health, fertility and quality of life of those affected<sup>1</sup>. Both present symptoms related to menstruation - with heavy, irregular, and sometimes painful periods being the most common. It is important to be able to differentiate these two diseases as both require different treatments.

## COMPARISON BETWEEN ENDOMETRIOSIS AND PCOS

Endometriosis	PCOS
Background	
It is a condition where endometrial glands and stromal cells (tissues of endometrial lining) exist outside of the uterine cavity, typically concentrating within the pelvic region <sup>2</sup> .	It is a hormonal/metabolic disorder with 3 principals feature, which include androgen excess, ovulatory dysfunction, and/or polycystic ovaries <sup>3</sup> .
Main site affected	
Ovaries, fallopian tubes and the tissue lining of pelvis <sup>4</sup> .	Ovaries
Sex hormone involvement <sup>6</sup>	
Excessive estrogen	Excessive androgen

Pathophysiology	
Endometriosis results when ectopic endometrial cells implant, grow into tissue, and elicit an inflammatory response <sup>2</sup> . These tissue thickens, breaks down and bleeds with each menstrual cycle. The tissue has no way to exit the body and becomes trapped, irritating surrounding tissue and eventually causing scar tissue and pelvic adhesions <sup>4</sup> .  In a person with endometriosis, two transcription factors, steroidogenic factor-1 (SF1) and estrogen receptor-β (Erβ) are upregulated in ectopic stromal/stem endometrial cells causing overproduction of prostaglandin E2 (PGE2) and formation of large quantities of estrogen (E2). These then leads to inflammation which trigger symptoms in patient with endometriosis. GATA-binding factor-6 (GATA6) are unmethylated and expressed abundantly in the ectopic endometrial cell, . modulating survival and proliferation of these cells together with Erβ <sup>6</sup> .	Genetic predisposition to excess ovarian androgen secretion is the main cause of hyperandrogenemia in PCOS.  Excess ovarian androgen secretion has both a direct effect on the ovarian alterations (polycystic ovary) [1] and an increasing effect on pituitary luteinizing hormone (LH) pulse frequency and amplitude, with relative low follicle stimulating hormone (FSH) secretion. In turn, adrenal androgens contribute to PCOS androgen excess [2] <sup>7</sup> . Insulin resistance with compensatory hyperinsulinemia (which may not occur in all PCOS patient) also enhances ovarian androgen production [3] as well as decreases production of sex hormone binding globulin (SHBG) in the liver [4], and both increase the pool of bioavailable androgens <sup>8</sup> .

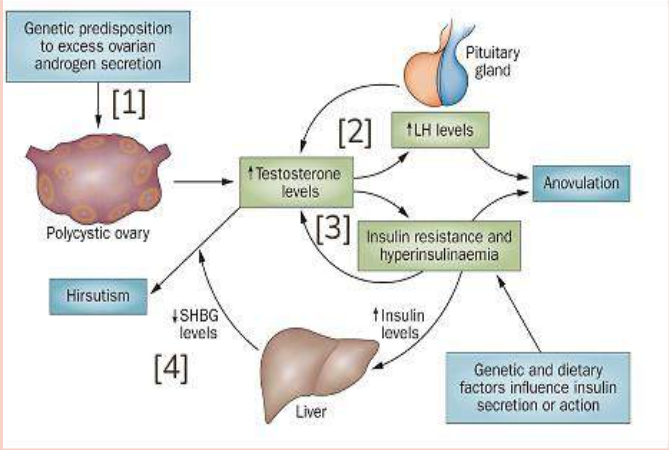
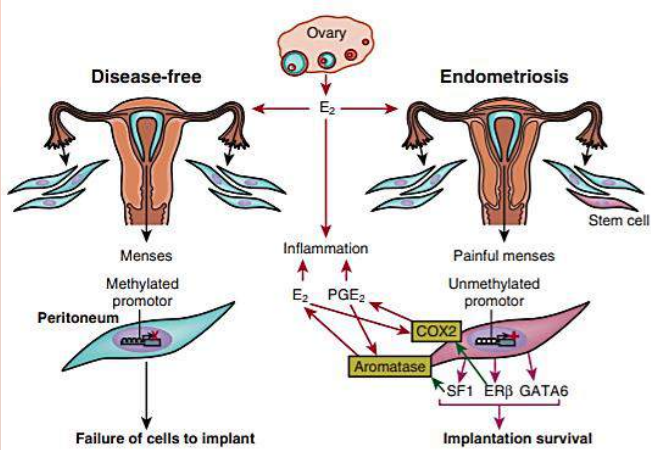


Figure 1. Summary of interactions between stem cells, DNA methylation, nuclear receptors, and inflammation in endometriosis<sup>6</sup>

Figure 2. Pathophysiology of PCOS<sup>7</sup>



COMPARISON BETWEEN ENDOMETRIOSIS AND PCOS

Endometriosis	PCOS
Symptoms	
Painful sex, pelvic or abdominal pain, fatigue, cramps, bloating, nausea <sup>2</sup>	Hirsutism, weight gain, acne, mood swings, depression, ovarian cysts <sup>3</sup>
Shared symptoms: Menstrual pain, Heavy menstrual bleeding, Irregular/missed period, Infertility	
Treatment <sup>5</sup>	
More focused on reducing estrogen and relieving pain	More focused on causing ovulation and decrease androgens

PHARMACOLOGICAL TREATMENTS FOR ENDOMETRIOSIS

HORMONAL THERAPY	
Combined oral contraceptives	
Medication	Mechanism of action
<b>Combined oral contraceptive pills</b> 1 tablet a day, as directed <sup>9</sup>	It contains estrogen and progestogen which suppresses ovarian function. Continuous progestin administration leads to decidualized endometrial tissue and slow progression of disease <sup>10</sup>
Progestin only therapy	
Medication	Mechanism of action
<b>Dienogest</b> 2mg od <sup>9</sup> <b>Dydrogesterone</b> 10-30mg od <sup>11</sup> <b>Norethindrone</b> 5-15mg od <sup>9</sup> <b>Medroxyprogesterone</b> 10mg tds <sup>12</sup> <b>Depot Medroxyprogesterone</b> 150mg every 3 months <sup>12</sup> <b>Intrauterine Levonogestrel (off label)</b> 52mg every 5 years <sup>12</sup>	Progestin mimic the effect of progesterone in the body. It suppress the growth of endometrial implant by inducing atrophy within ectopic endometrium. <sup>10</sup>
GnRH Agonist <sup>12</sup>	
Medication	Mechanism of action
<b>Goserelin</b> SC 3.6mg every 28 days <b>Leuprorelin</b> IM 3.75 mg monthly or IM 11.25 mg every 3 months, maximum 6 months <b>Naferelin Nasal Spray</b> 200mcg bd for 6 months	It stimulates synthesis of FSH and LH from pituitary gland. Continuous administration inhibits gonadotrophin production, resulting in low estrogen and progesterone levels.
Danazol <sup>13</sup>	
Medication	Mechanism of action
<b>Danazol</b> 200-800mg/day in 2 divided dose, depending on severity for maximum 9 months	It acts as an anterior pituitary suppressant by inhibiting the pituitary output of gonadotropins, FSH & LH. It also has androgenic properties.

## PHARMACOLOGICAL TREATMENTS FOR PCOS

Symptom	Management	Dose	Remarks	Mechanism of action
Irregular menstrual	<b>Combined oral contraceptive</b> (first line therapy)	1 tablet a day	Low-dose preparations with minimal androgenic potential (eg Norgestimate, Desogestrel, Gestodene, Drospirenone, Dienogest and Ethinyl estradiol or equivalent) are preferred for long-term management <sup>14</sup> .	COC suppress androgen production, thus ameliorating skin androgenic symptoms and improving menstrual dysfunction <sup>15</sup> .
	<b>Progestin</b> <sup>16</sup>	As per medication	Alternative treatment for endometrial protection are intermittent or continuous progestin therapy Medroxyprogesterone acetate: 5-10mg od 10 to 14 days every 1-2 months Norethindrone: 0.35mg daily	Progestin leads to thickening in the lining of the uterus. Taking cyclic progesterone, uterine lining will be sloughed off and bleeding begins.
Hirsutism	<b>Spirolactone</b> (off label)	50-100mg bd	The first line therapy is COC. If without symptom improvement after ≥6 months of COC use and cosmetic treatment, combination of COC and anti androgen (Spirolactone, Finasteride) is considered <sup>16</sup> .	Spirolactone is a nonspecific androgen-receptor blocker <sup>17</sup> .
	<b>Finasteride</b> (off label)	2.5-5mg od		Finasteride is a 5- $\alpha$ reductase inhibitor which acts by inhibiting the conversion of testosterone to dihydrotestosterone and by blocking androgen receptor <sup>17</sup> .
Obesity	<b>Weight loss</b> <sup>16</sup>	N/A	Lifestyle changes such as exercise and reduced calorie intake is recommended for patient who is overweight	N/A
Insulin resistant/ Diabetes	<b>Metformin</b> <sup>16</sup>	1.5-2g daily in 2-3 divided dose	Second line therapy. Consider in PCOS patient with diabetes mellitus and who are insulin resistant.	Metformin decrease the serum lipids, androgen and insulin, thus induce ovulation and regular menstrual cycle.
Dyslipidemia	<b>Statin</b> <sup>16</sup>	As per medication	Effective for dyslipidemia in women with PCOS	Inhibition of HMG-CoA reductase results in both reduction in cholesterol synthesis and serum androgen levels
Reduced fertility	<b>Letrozole</b> <sup>16</sup> (off label)	2.5-7.5mg for 5 days, up to 5 cycles	First line therapy for obese women with PCOS.	Letrozole is an aromatase inhibitor used to induce ovulation by locking estrogen production, leading to increase in FSH release.
	<b>Clomiphene</b>	50-100mg od for 5 days, maximum 6 cycles <sup>17</sup>	First line treatment for ovulation induction when fertility is desired <sup>16</sup> .	A selective estrogen receptor modulator, binds to estrogen receptors, inducing ovulation by increasing the output of pituitary gonadotropins <sup>17</sup>

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## Apa yang diketahui mengenai VOC OMICRON?



Omicron menyebabkan kes yang tinggi seperti yang berlaku di Afrika Selatan. **Varian ini mengandungi 45 – 52 mutasi pada keseluruhan genom; 26 – 32 mutasi pada spike protein**



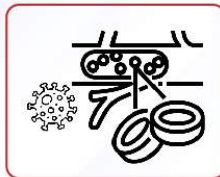
Sesetengah daripada mutasi ini juga dijumpai pada VOC Alpha, Beta, Gamma dan Delta. **Terdapat beberapa mutasi yang dikaitkan dengan:**



**S-gene target failure pada ujian PCR\***



**Peningkatan kebolehjangkitan**



**Peningkatkan kebolehan virus untuk melekat pada sel badan**



**Pengurangan respon antibodi**

**\*Kaedah PCR masih dapat mengesan VOC Omicron. Satu petanda bahawa virus yang dikesan adalah VOC Omicron adalah sekiranya S-gene tidak dikesan**

## Apa yang diketahui mengenai VOC OMICRON?

**1** VOC Omicron telah menular pada kadar yang lebih pantas daripada varian lain. Ini menunjukkan kemungkinan besar ianya lebih mudah merebak



**2** Belum diketahui sama ada jangkitan VOC Omicron menyebabkan penyakit yang lebih teruk berbanding VOC lain



**3** Kaedah rawatan pesakit masih sama



**4** VOC Omicron belum diketahui sama ada akan mengurangkan keberkesanan vaksin COVID-19 yang sedia ada

**5** Sekiranya perlu, penyesuaian kepada komposisi vaksin sedia ada akan dibuat bagi meningkatkan keberkesanan vaksin



**Kementerian Kesihatan Malaysia akan terus melakukan surveilan genomik bagi mengesan VOC Omicron ini**



**Kementerian  
Kesihatan  
Malaysia**



**Agenda Nasional  
Malaysia Sehat**



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**sihatmilikku**



**SCAN ME**

PALIPERIDONE 350MG/1.75ML PROLONGED-RELEASE FOR INTRAMUSCULAR INJECTION

DESCRIPTION

It is an intramuscular, extended- release injectable suspension of atypical antipsychotic indicated for the treatment of schizophrenia in patients after they have been adequately treated with 1-month paliperidone palmitate. The active ingredient, paliperidone palmitate, is a psychotropic agent belonging to the chemical class of benzisoxazole derivatives.

REGISTRATION NUMBER

MAL20046069AZ

PRICE

RM 2,525.35/1's

DEPARTMENT

Psychiatry

PRESCRIBER CATEGORY

A\* ( Consultant/Specialist for specific indications only)

PREGNANCY CATEGORY

Category C (MIMS)

MECHANISM OF ACTION

Paliperidone palmitate is hydrolyzed to paliperidone. The mechanism of action of paliperidone as with other drug having efficacy in schizophrenia, is unknown. It has been proposed that the therapeutic activity of paliperidone in schizophrenia is mediated through a combination of central dopamine Type 2 (D2) and serotonin Type 2 (5HT2A) receptor antagonism.



INDICATION IN FUKKM

For the maintenance treatment of schizophrenia in adult patients who have been adequately treated with the 1-month paliperidone palmitate injectable product for at least four months.

DOSE AND ADMINISTRATION

Apply 3.5 as a dose multiplier to the previous 1-month injection dose and administer every 3 months (FUKKM)

IM Inj once every 3 month, may be adjusted every 3 month in increments of 175-525 mg based on tolerability and/or efficacy (MIMSGATEWAY)

USE IN SPECIFIC POPULATIONS

**Paediatric** : Not recommended in pediatric patients because of the potential longer duration of an adverse event compared to shorter-acting products.

**Pregnancy:** May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure.

**Nursing:** Can pass into human breast milk. The benefits of breastfeeding should be considered along with the mother's clinical need for treatment.

**Renal impairment:**  
**CrCl >50mL/min** : Not recommended.  
**CrCl ≥ 50 mL/min to < 80 mL/min:** Based on the previous dose of the 1-month paliperidone palmitate extended-release injectable suspension.

**Hepatic impairment:**  
**Mild to moderate hepatic impairment** : No dose adjustment is required.  
**Severe hepatic impairment** : Paliperidone has not been studied.



## PRECAUTIONS

**Cerebrovascular Adverse Reactions:** Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack, including fatalities). **It is not approved for use in patients with dementia-related psychosis.**

**Neuroleptic Malignant Syndrome (NMS):** A potentially fatal symptom complex has been reported.

**QT Prolongation:** Paliperidone causes a modest increase in the corrected QT (QTc) interval.

**Tardive Dyskinesia (TD) :** Elderly female patients appeared to be at increased risk for TD although it is impossible to predict which patients will develop the syndrome. Discontinue drug if clinically appropriate. The syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

**Metabolic Changes:** These metabolic changes includes hyperglycemia and diabetes mellitus, dyslipidemia and weight gain. May also increase cardiovascular/cerebrovascular risk.

**Orthostatic Hypotension and Syncope:** Use with caution in patients with known cardiovascular or cerebrovascular disease and patients predisposed to hypotension.

**Falls :** Particularly the elderly. Assess the risk of falls when initiating antipsychotic treatment and recurrently for patients on long-term antipsychotic therapy.

**Leukopenia, Neutropenia, and Agranulocytosis:** Monitor complete blood count in patients with a history of low white blood cell count (WBC) or a drug-induced leukopenia/neutropenia.

**Hyperprolactinemia:** Prolactin elevations occur and persist during chronic administration.

**Potential for Cognitive and Motor Impairment:** Use caution when operating machinery.

**Seizures:** Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold.

## CONTRAINDICATIONS

Patient with known hypersensitivity to paliperidone, risperidone or to any of the components in the formulation.

## ADVERSE REACTIONS

### COMMON :

**Dermatologic:** Injection site reaction (Up to 12%)

**Endocrine metabolic:** Hyperprolactinemia (32-55.6%), weight gain (5.8-18.4%)

**Neurologic:** Akathisia (1-6%), dizziness (1-6%), extrapyramidal disease (12%), headache (6-15%), parkinsonism (4-18%), somnolence,

**Psychiatric:** Agitation (4-10%)

### SERIOUS :

**Cardiovascular:** Orthostatic hypotension (<1%), prolonged QT interval, syncope (<1%),

**Hematologic:** Agranulocytosis, leukopenia, neutropenia

**Immunologic :** Anaphylaxis (rare)

**Neurologic :** Seizure (<1%), tardive dyskinesia, tonic-clonic seizure (<1%)

**Reproductive:** Priapism

**Other:** At risk for imbalance body temperature, neuroleptic malignant syndrome

## STORAGE

Do not store above 30°C.

## PHARMACIST ROLES

- Advise patient to follow the treatment schedule (once every 3 months).
- Advise patient to report immediately any unusual symptoms such as high fever, severe muscle stiffness, confusion, loss of consciousness, changes in breathing, heartbeat and blood pressure.
- Advise patient to not drive or operate machinery during the course of treatment.

## REFERENCES

Product leaflet, MIMS, FUKKM, rxlist.com, Micromedex.



# Somatropin 10mg (30IU) Injection

## A. DESCRIPTION

Somatropin is produced by DNA recombinant technology bearing the gene for human growth hormone. It is used as growth replacement therapy for people with inadequate growth hormone.

## B. REGISTRATION NUMBER

MAL20102068AZ

## C. PRICE

RM 462.75 / Each

## D. DEPARTMENT

Endocrine

## E. PRESCRIBER CATEGORY

A\* - Consultant / specialists for specific indications only

## F. PREGNANCY CATEGORY

Category C (MIMS)

## G. MECHANISM OF ACTION

Somatropin binds to dimeric growth hormone (GH) receptors causing induction of transcription and translation of GH-dependent proteins which include insulin-like growth factor 1 (IGF-1), IGF BP-3, and acid-labile subunit. Tissue and metabolic effects either direct or mediated indirectly by IGF-1, include stimulation of chondrocyte differentiation and proliferation, stimulation of hepatic glucose output, protein synthesis and lipolysis. It works by stimulates linear growth and increase growth rate by increasing nitrogen retention, stimulation of skeletal muscle growth and mobilization of body fat to maintain a normal body composition.



## H. INDICATION IN FUKKM

### To be used in children for:

- Growth failure due to inadequate endogenous growth hormone.
- Growth failure in girls due to gonadal dysgenesis (Turner syndrome).
- Growth failure in short children born small gestational age (SGA).

### To be used in adult for:

- Pronounced growth hormone deficiency (GHD) in known hypothalamic-pituitary disease.
- Childhood onset growth hormone insufficiency.

## I. DOSE AND ADMINISTRATION

- 0.7 – 1 mg/m<sup>2</sup>/day or 0.025 – 0.035 mg/kg/day SC/IM.
- 1.4 mg/m<sup>2</sup>/day or 0.045 – 0.050 mg/kg/day SC.
- 1 mg/m<sup>2</sup>/day or 0.035 mg/kg/day.

### For adult:

- For replacement therapy: The dosage must be adjusted to the need of the individual patient.
- Childhood onset GHD: The recommended dose to restart is 0.2-0.5 mg/day with subsequent dose adjustment based on IGF-I concentration determination.
- Adult-onset GHD: It is recommended to start low dose 0.1-0.3 mg/day and to increase the dosage gradually at monthly intervals in order to meet the need of the individual patient. Serum IGF-I can be used as guidance for the dose titration. Women may require higher doses than men, with men showing an increasing IGF-I sensitivity over time. This means that there are risk dose requirements decline with age. Maintenance dosages vary from person to person, but seldom exceed 1.0 mg/day (equal to 3IU/day).

**J. ADVERSE REACTIONS****COMMON**

- **Cardiovascular:** Edema of lower extremity (15%), Peripheral edema (up to 42%)
- **Hematologic:** Eosinophil count raised (11% - 12%), Hematoma (9%)
- **Musculoskeletal:** Arthralgia (6% - 27%), Myalgia (Adult up to 15%, paediatric 5.7% - 24.3%)

**SERIOUS**

- **Cardiovascular:** Disorder of cardiovascular system (1%), Edema (Adult up to 41%, paediatric up to 4%)
- **Endocrine metabolic:** Diabetes Mellitus, (up to 5%), Hypothyroidism (16% - 25%), Impaired glucose tolerance (6%)
- **Otic:** Otitis media (paediatric up to 86.4%)

**K. CONTRAINDICATIONS**

- In patient with acute critical illness due to surgery.
- Hypersensitivity to Somatropin and other excipients.
- If any evident of tumor growth.
- In children with closed epiphyses / with Prader-Willi Syndrome (PWS), severe obesity and respiratory disorder.

**L. USE IN SPECIFIC POPULATIONS**

- **Geriatric use:** Limited data for >60 years of age. Start with lower dose and increase in smaller dose.
- **Pregnancy:** Inadequate study in pregnancy. The use should be avoided.
- **Breastfeeding:** No clinical studies. The use should be avoided.

**M. PRECAUTIONS**

- **Administration:** Lipoatrophy may occur, rotate site of injection to reduce risk.
- **Cardiovascular:** Patient with Turner Syndrome has higher risk of cardiovascular disease (such as hypertension, stroke and aortic aneurysm). Fluid retention is usually dose dependent in adult patient.
- **Endocrine and metabolic:** New or worsening hyperglycemia, glucose intolerance or diabetes mellitus especially in patients with risk factors for diabetes.

**N. STORAGE**

2 – 8 °C (Refrigerated)

**O. PHARMACIST ROLE**

- Advice patient to let the doctor know if taking any hormone medications or planning to have children.
- Counsel patient on the correct way to administer, store, discard and to always rotate injection site.
- To monitor occurrence of any side effects after starting the medication for example glucose level, thyroid function test, unusual growth or potential malignancy.
- Advice patient to report any symptoms of fluid retention, hypoadrenalism or intracranial hypertension.
- Remind patient to report any changes in behavior such as onset of headaches, vision disturbance or changes in skin pigmentation.

**P. REFERENCES**

Product information leaflet, FUKKM, QUEST3+, MIMSGateway, UpToDate

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## Pharmacy R&D

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### AUTHORS

Mohamed S, Chan MF,  
Yew JM, Kori AN, Abdul  
Wahab S, Mohd Ali Z

Department of Pharmacy,  
Hospital Tengku Ampuan  
Afzan, Kuantan.

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### TITLE:

## EVALUATION OF AN INITIATION REGIMEN OF WARFARIN FOR INTERNATIONAL NORMALIZED RATIO TARGET 2.0 TO 3.0

### INTRODUCTION

The number of patients on warfarin therapy is rising steadily. Although warfarin is beneficial, it carries a high risk of bleeding, especially if the international normalized ratio (INR) values exceed 3.0. Currently, no warfarin initiation regimens have been developed for the Asian population, especially for Malaysians.

### OBJECTIVE

This article describes the efficacy and safety of a new initiation regimen for warfarin among warfarin-naïve patients.

### METHODOLOGY

Data were retrospectively collected from the ambulatory and inpatient settings.

### RESULTS

A total of 165 patients who each had a target INR of 2.0 to 3.0 were included in the study. The mean age was 57.2 years and 94 patients were male. A total of 108 patients used Regimen 1 (5 mg/5 mg/3mg) and the rest of the patients used Regimen 2 (5 mg/3 mg/3 mg). Most patients used warfarin either for atrial fibrillation (52.1%) or for venous thromboembolism (29.7%). Overall, 88 of the patients had INR values above 50% from the baseline on Day 4. Additionally, 13 patients had INR values of  $>3.2$ , which required withholding and lower dose of warfarin. The predicted weekly maintenance warfarin dose ( $23 \pm 0.5$  mg/week) was found to have correlated closely with the actual maintenance dose ( $22.8 \pm 0.5$  mg/week;  $r^2 = 0.75$ ). Nearly two thirds (70.3%) of the patients achieved the target INR on Day 11.

### CONCLUSION

The warfarin initiation regimens in this study was simple, safe, and suitable to be used in both ambulatory and inpatient settings for managing warfarin therapy.





## AUTHORS

Ahmad Z, Tan YS,  
Mohd Saad NA, Chase-  
Currier A, Mazha HN,  
Mohammad  
Fakhruddin NH, Ahilan  
T

Department of Pharmacy,  
Hospital Tengku Ampuan  
Afzan, Kuantan.



## TITLE:

# PERCEPTION OF PHARMACY STAFF IN HOSPITAL TENGKU AMPUAN AFZAN TOWARDS FACTORS CONTRIBUTING TO DISPENSING ERRORS

## INTRODUCTION

There are various factors that could contribute to dispensing error in pharmacy department. These factors have been identified by a few studies and can be sorted into a few categories such as workload, working environment, skills and knowledge, drug designs as well as the communication between staff.

## OBJECTIVE

This study aimed to identify the perceptions of the factors that contributed to dispensing errors among the pharmacy staff in Hospital Tengku Ampuan Afzan (HTAA), Kuantan.

## METHODOLOGY

A cross-sectional study using a set of validated questionnaires which involved pharmacists, pharmacy assistants and provisional registered pharmacists who are working in pharmacy department HTAA regardless of their working service and experience. Likert scale and rating scale was used to answer for possible error cause and contributing factors and suggestion to reduce dispensing error. Data was presented in frequency and percentage. As for the rating scale, data was presented in mean rank and percentage of scale maximum (%SM).

## RESULTS

A total of 144 correctly answered questionnaire were enrolled and analyzed. The results showed that 76.4% of the pharmacy staff had committed dispensing errors before. Highest dispensing errors committed were dispensing wrong drug (22.3%) followed by giving wrong drugs strength (15.9%) and wrong quantity (10.6%), having wrong drug name or label (9.6%), and giving to the wrong patient (9.3%). Meanwhile, factors contributing to dispensing errors identified were distraction (97.9%), stress (95.8%), illegible prescription (95.8%), and similar drug names (95.8%) and similar drug packaging (95.1%). The contributing factors were further categorized to four main causes and from the rating scale it revealed that the main cause to dispensing error was staff related cause (30%SM), due to inadequate knowledge about the drug, distraction and fatigue. This was followed by medication related (42%SM), working environment (55%SM) and task and technology related cause (73.33%SM). The highly rated strategy to reduce dispensing errors was double checking the prescription with reference book and senior officer before dispensing the medication (24.43%SM).

## CONCLUSION

Dispensing errors commonly occurred during supplying medication and staff factor was the main cause to error committed and most preferable strategies to prevent errors are counterchecking, adequate staffing and legible prescription.

# GOODBYE PUAN ZAIDAH



We will miss you...



**Farmasi Klinik Pakar**  
**13 October 2021**



Pn Zaidah together with the staff from Farmasi Klinik Pakar



Pn Mastura, Pn Zawiah and Ms Tou giving a token of appreciation to Pn Zaidah from Inpatient Department



Pn Aryani, Head of Farmasi Kecemasan presenting a token of appreciation to Pn Zaidah





*Thank you for your  
patience and guidance.*

## KEY POINTS

### TODAY'S AGENDA

- presented with BPSD
- **BPSD** are core features of dementia that affect the overall management plan of PLWD with multiple etiologies
  - **Factors contribute to BPSD** - look at Patient, Caregiver and Environmental cause because it can be reversible and manage without drugs
  - **Strategy Plan : DICE**
    - Drugs used for BPSD only indicated if PLWD harmful to themselves or others
    - Psychoactive agent : PIMs Use as short term
    - Watch-out for PIMs - antipsychotic is NO NO.
  - **Pharmacist Role** : Understand , Identify DRP , Reduce Harm, Monitor, Counsel, Educate, Support



# KURSUS PHARMACY UPDATES 2021

The speakers for the day included Ms Ng Sin Ye, Pn Siti Husna Izzati bt Othman, Pn Amnah bt Berdal and Pn Liyana Hamiza bt Abdul Karim.

More than 50 participants attended the course.

Online Platform  
16 October 2021  
8:30am-12:00pm

**10 warning signs of dementia**

1. Memory Loss
2. Difficulty performing familiar tasks
3. I DENT' ROMED BIR (Problems with language)
4. Disorientation to time and place
5. Poor or diminished judgement
6. Problems keeping track of things
7. Misplacing things
8. Changes in mood and behaviour
9. Trouble with images and spatial relationships
10. Withdrawal from work or social activities

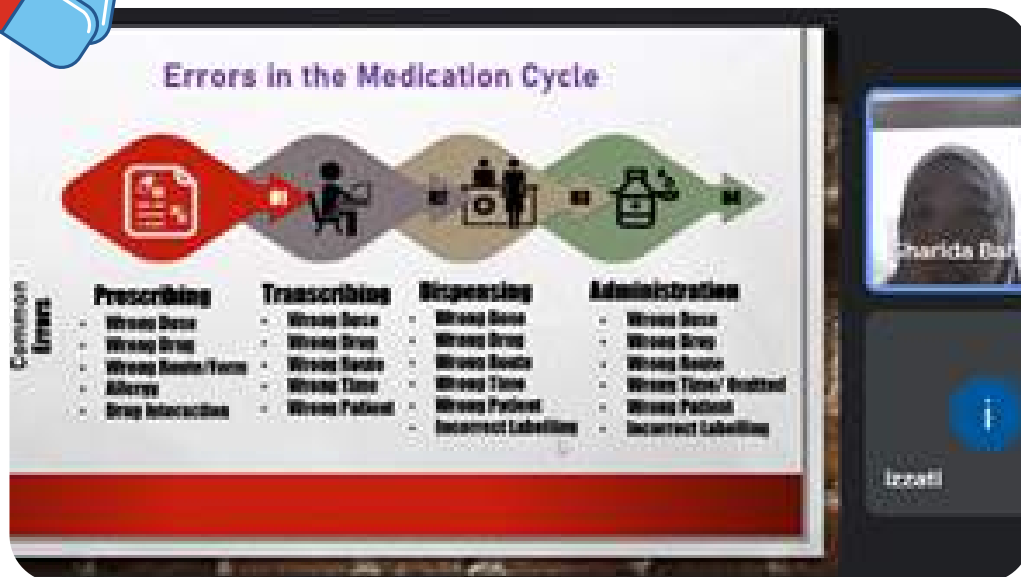
**Dementia is not a part of normal ageing.**  
Talk to a doctor or contact Alzheimer's Disease Foundation Malaysia (ADFM) for more information.





# KURSUS MEDICATION SAFETY

ONLINE PLATFORM, 27 OCTOBER 2021

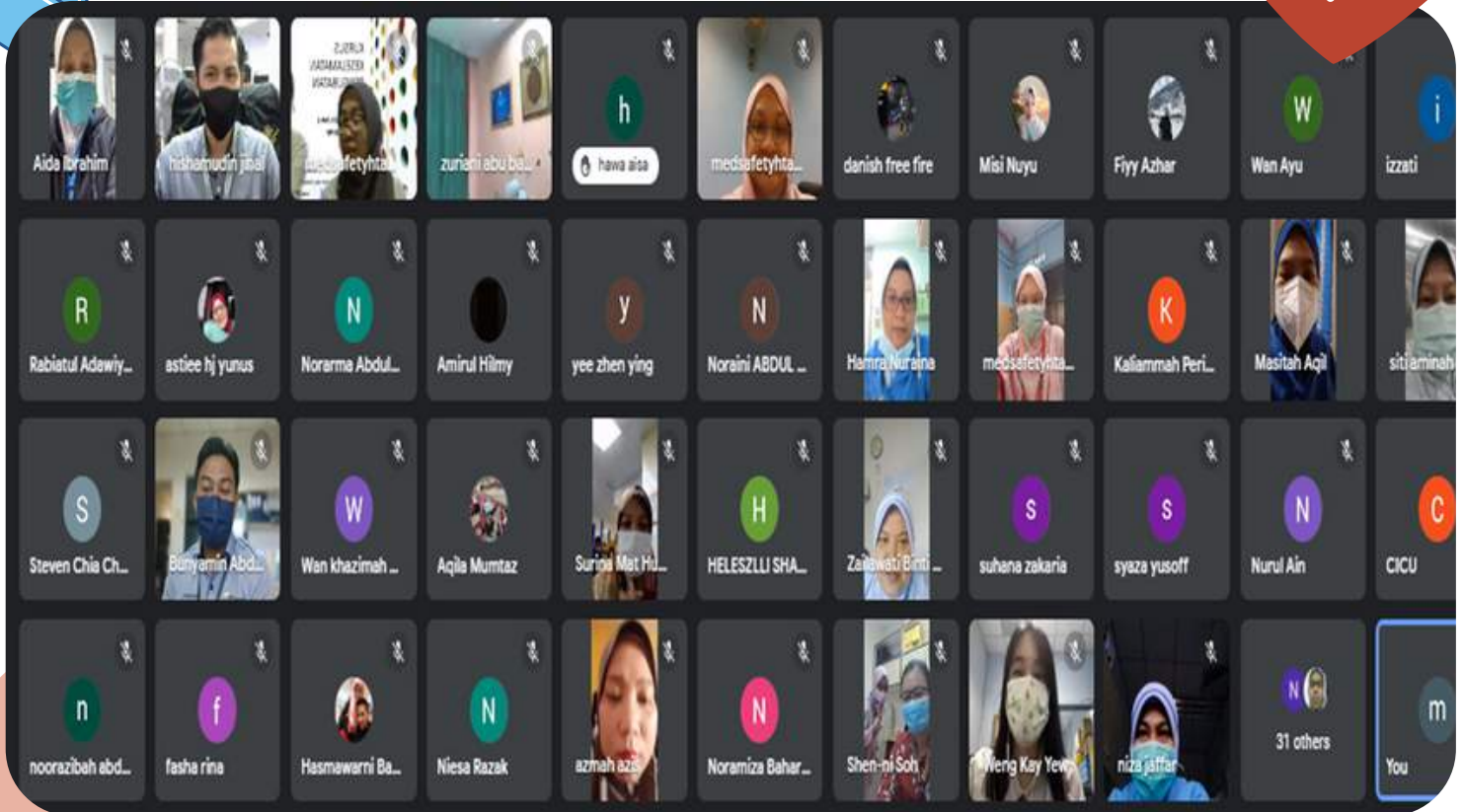


Pn Noor Wahida sharing on 'Minimizing Potential Medication Errors'

Dr Bunyamin of Unit Kualiti elaborating on 'The Physician's Role in Patient Safety'







Participants of  
the day



Prizes for the winners of the best  
medication safety board



# MEDICATION SAFETY BOARD CONTEST WINNERS



1st Place:  
Kenanga 6C



2nd Place:  
Kiambang 5C



3rd Place:  
ENT Clinic



1

Bagaimana saya boleh melindungi diri saya  
dan keluarga saya daripada jangkitan

# VOC OMICRON?

- 1** Tangguhkan perjalanan ke negara yang berisiko tinggi berlaku penularan VOC Omicron. Adalah dinasihatkan untuk sentiasa merujuk laman web KKM atau WHO untuk mendapat senarai terkini.



07:30	MALAWI	CANCELLED
09:10	ANGOLA	CANCELLED
10:45	BOTSWANA	CANCELLED
11:15	ZIMBABWE	CANCELLED
12:05	MOZAMBIQUE	CANCELLED

- 2** Terus mengamalkan langkah-langkah kesihatan awam sendiri berikut:



✓ Pakai pelitup muka



✓ Jaga penjarakan fizikal



✓ Kerap cuci tangan atau menggunakan hand sanitizer



✓ Amalkan etika batuk dan bersin



✓ Elakkan tempat yang sesak dan sempit



✓ Pastikan pengudaraan yang baik

- 3** Dapatkan vaksin COVID-19, termasuk dos penggalak yang boleh mencegah penyakit teruk dan kematian akibat COVID-19.



2

Bagaimana saya boleh melindungi diri saya  
dan keluarga saya daripada jangkitan

# VOC OMICRON?

- i** Sekiranya bergejala atau kontak rapat, buat ujian sendiri



- 4** Laksanakan TRIIS

- ii** Laporkan keputusan ujian sama ada positif atau negatif dalam aplikasi MySejahtera



- iv** Sekiranya positif, maklumkan kepada kontak rapat anda supaya mereka juga mengambil tindakan kuarantin sendiri dan membuat ujian sendiri



- iii** Asingkan diri sekiranya keputusan positif atau merupakan kontak rapat



- v** Dapatkan rawatan sekiranya gejala bertambah teruk



\* Dapatkan maklumat sahih dari laman web WHO, US CDC, portal KKM dan lain-lain sumber media rasmi yang boleh dipercayai



Kementerian  
Kesihatan  
Malaysia



Agenda Nasional  
Malaysia Sihat



myhealthkkm



sihatmilikku



SCAN ME



# Farewell

# 2021



Don't stop believing

# HELLO 2022!

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