

# #iGotMyShot

VACCINATION<sup>SG</sup>

## Safety and Quality Processes for COVID-19 Vaccination in SG

IMSN Vaccine Safety Interest Group (6 May)



# Outline

01

## **Scheduling & Screening**

Ensuring timely doses and accurate triaging

02

## **Vaccine Preparation**

Reducing storage and dilution errors

03

## **Vaccinator Training**

Administering vaccines safely

04

## **SAE and Incident Management**

Monitoring and managing patients post-vaccination

## Internationally, there have been reports of vaccination errors occurring at different stages of the workflow

**01**

### Scheduling & Screening

- a. Administer vaccine to contraindicated groups (e.g. pregnant women, patients who are severely immunocompromised)
- b. Book second dose too early or too late

**02**

### Vaccine Preparation

- a. Compromised cold chains
- b. Incorrect volume of diluent or undiluted vaccine
- c. Expired vaccines
- d. Mix-up of similar looking vials (e.g. Moderna COVID-19 vaccine vs. Regeneron's monoclonal antibody)

01

**Scheduling and screening errors are reduced by requiring individuals to book appointments via a system which checks for duration (both doses are booked at the same time) and contraindications**

## 1. Receive booking link

**COVID-19**  
Vaccination Registration

REGISTER FOR THE VACCINE

Registration code  
Enter the 10-character code sent to you via SMS

NRIC/FIN

**GET STARTED**

🕒 Estimated 10 mins to complete

## 2. Complete questionnaire

Gender  
 Female  Male

**Your Medical Status**

IMMUNOCOMPROMISE

Do you have any medical conditions causing severe immunocompromise?  
For example:

- Recent transplant in the past 3 months
- On cancer treatment (immunotherapy / chemotherapy / radiotherapy) less than 3 months ago OR planned in the next 2 months
- Immunotherapy for non-cancer conditions (e.g. rituximab, etc)
- HIV, with CD4 count less than 200

Yes  No

ALLERGIES

Have you ever had any life-threatening allergic reactions? (to vaccines, medications, insect stings, food, etc.)

Yes  No

Have you ever been prescribed with an Epi-Pen? (self-injected epinephrine for severe allergy)

Yes  No

Have you ever had severe skin rash AND mouth/genital ulcers/red eyes/liver injury due to medications? (TEN/SJS/DRESS/DIHS)

Yes  No

PREGNANCY & RELATED QUESTION (FOR FEMALES ONLY)

Are you currently pregnant, or suspect that you are pregnant?

Yes  No

## 3. Book appointment

[Print Booking Details](#)

All set!

Name  
NRIC

Clementi Community Centre  
220 Clementi Ave 4, Singapore 129880

1st appointment

09 May 2021, Sunday  
10:30 AM

2nd appointment

30 May 2021, Sunday  
10:30 AM

### Important Reminders

To ensure that we can serve you:

Bring your NRIC or FIN for both appointments

01

At the vaccination site, the staff is then required to conduct another eligibility screening and verify the date of the 1<sup>st</sup> dose (where applicable)

#### 4. Complete on-site screening

#### 5. Receive vaccine

#### 6. Stay for observation

MOH COVID-19 VACCINATION FORM - FORM 1  
TO BE COMPLETED BY PATIENT (please approach our staff if you need help)  
卫生部2019冠状病毒疫苗接种表格 - 表格 1  
此表格由病患填写(如需协助, 请向我们的职员求助)

PART A: PERSONAL PARTICULARS A部分: 个人资料				Queue 等候	Registration 登记
NAME (BLOCK LETTERS): 姓名(大写):		NRIC No./Foreign Identification No.(FIN): 身份证/外国身份证号码:			
Gender: 性别: <input type="checkbox"/> Male 男 <input type="checkbox"/> Female 女	Date of Birth (dd/mm/yyyy): 出生日期(日/月/年):	Age: 年龄:	Ethnic Group: 种族: <input type="checkbox"/> Chinese 汉族 <input type="checkbox"/> Indian 印度族 <input type="checkbox"/> Malay 马来族 <input type="checkbox"/> Others 其他	Residential Status: 居民身份: <input type="checkbox"/> Citizen 公民 <input type="checkbox"/> Permanent Resident 永久居民 <input type="checkbox"/> Long term 长期准证持有者 <input type="checkbox"/> Other 其他	
Address*: 住址*:  Postal Code: 邮政编号:			Handphone Number: 手机号码:  Email Address*: 电邮地址*:		
PART B: MEDICAL INFORMATION B部分: 医疗信息				Waiting Area 等候区	
PART B1: FEVER & VACCINATION B1部分: 发烧及疫苗接种				NO 否	YES 是
Have you had a fever or any vaccination recently? 你最近是否有发烧或接种过任何疫苗?					
• Fever (Temperature $\geq 37.5^{\circ}\text{C}$ ) in the past 24 hours? 在过去24小时内发烧(体温达 $37.5^{\circ}\text{C}$ )?				<input type="checkbox"/>	<input type="checkbox"/>
• Any vaccination in the past 14 days? 在过去14天内接种过任何疫苗?				<input type="checkbox"/>	<input type="checkbox"/>
PART B2: IMMUNOCOMPROMISE B2部分: 免疫功能低下				NO 否	YES 是
Do you have any medical conditions causing severe immunocompromise? For example: 你是否有任何会导致免疫功能严重低下的病症? 例如:				<input type="checkbox"/>	<input type="checkbox"/>
• Recent transplant in the past 3 months 在过去三个月内进行过移植手术					
• Active cancer not in remission 未抑制活性癌细胞					
• On cancer treatment (immunotherapy / chemotherapy / radiotherapy) 正在接受癌症治疗(免疫疗法/化疗/放射治疗)					
• HIV with CD4 count < 200 爱之病, CD4细胞计数低于200					
PART B3: ALLERGIES B3部分: 过敏史				NO 否	YES 是
Have you ever had any severe allergic reactions to medicines, vaccines, or food?					



# 02 Vaccination providers are required to adhere to strict storage and labelling protocols to minimise mix-ups

## 1. Storage

- Undiluted vaccine vials should be stored in the fridge with temp between 2 and 8 degrees Celsius, and must be monitored (either use temperature data logger or record temperature twice daily)
- SMS alert trigger system to at least 3 personnel is needed when vaccine refrigeration is running on Uninterrupted Power Supply (UPS) or if temperature deviates from range
- Vaccine vials should be protected from light
- Pre-filled dosing syringes must be stored with their corresponding vial (e.g. in a kidney dish) and labelled with date and time of dilution, extraction, and expiry
- Back-up Power Supply Plan is required

## 2. Handling and dilution

- First-in-first-out system is required when retrieving vials from fridge
- Vials are labelled with date and time of dilution and expiry
- Diluted vials must be clearly visually differentiated from undiluted vials, and placed separately to prevent mix-ups

Staff are also given visual guides to help distinguish between the vaccines\*

### PFIZER



- Purple Cap
- Smaller vial
- Dimension:
  - Height 30mm
  - Diameter 13mm

### MODERNA



- Red Cap
- Larger vial
- Dimension:
  - Height 50mm
  - Diameter 24mm

Both are multidose vials (min 5 for Pfizer, min 10 for Moderna) - Pfizer needs to be diluted with saline while Moderna does not

## 02 During vaccine prep, safeguards are in place to prevent handling, dilution and administration errors

### 2. Handling and dilution (continued)

- a. Staff should not be distracted during vaccine preparation
- b. When handing over duties, a handover checklist indicating date/time of dilution, dilution status, and pre-administration verification of patient and vaccine info may be employed
- c. Physically separate areas for dilution and administration are required
- d. Vaccinators must visually inspect vials for discolouration or particulates before/after dilution and before each syringe is filled

### 3. Administration

- a. Staff should not be distracted when administering
- b. Mandatory hand hygiene and aseptic technique
- c. Must check each dosing syringe for final volume, particulates and discolouration, air bubbles
- d. Vaccinators must perform Five Rights of Medication Administration before administering each dose (Right patient, Right drug, Right dose, Right route, Right time)

### 4. Role Designation

- a. Staff should not multitask and must have access to adequate rest time if performing critical functions
- b. Cross-deployment of staff who are assigned to perform critical functions should be minimised
- c. Quality & Safety Officer who is healthcare-trained should be contactable and present at all times

03

## Vaccinators are required to complete a Vaccinator Training Course (VTC) and competency assessment\*

### MOH's Vaccinator Training Toolkit

#### Toolkit for Training of Vaccinators

To help vaccination providers ensure the competency of their vaccinators, this toolkit has been assembled to provide information on the COVID-19 vaccines that are currently in use and baseline training requirements for persons assuming the role of vaccinators at their centres.

### Competency Assessment

Part 1: Off-site Training	
Theoretical component:	4 hours (include theory assessment) <i>Mode of learning may be via e-learning for the training hours</i>
Practical component:	6 hours (include simulated practice and assessment for the required skills)
<b>Total:</b>	<b>10 hours</b>
Part 2: On-site Training	
On-The-Job (OJT) Clinical component:	The OJT practice and assessment will require the learner to demonstrate the following skills competently: <ul style="list-style-type: none"> <li>• <u>3</u> successful vaccine reconstitutions, and</li> <li>• <u>5</u> successful administration of vaccines</li> </ul>

\*Some medical professions may be exempt from the training requirements



03

**In addition, MOH maintains tight communication channels with the vaccination sites to gather issues faced on the ground, suggest improvements, and disseminate updated guidance and workflows**

### **End-to-End Guidance for Vaccination Providers**

- Clinical guidance for screening
- Storage and handling of vaccines
- Dosage and administration
- Management of vaccine errors
- Reporting requirements

### **Other means of ground communication & feedback**

- **Regular ops instructions** to vaccination sites containing updated workflows
- Ad hoc **site inspections** by MOH to identify lapses in safety or quality protocols
- System for vaccination sites to **submit incident reports** to MOH (e.g. vaccine errors, supply chain problems, IT issues, service delivery issues)
- **Briefing sessions to share best practices** and areas for improvement

04


## In addition to the mandatory post-vaccination observation period of 30 minutes, all vaccination sites are required to be staffed and equipped to deal with medical emergencies

### Licensing Requirements for handling medical emergencies

- Vaccination providers are required to have **adequate and appropriate emergency drugs and facilities\*** which are fit for use (i.e. drugs must not be expired, and equipment must be serviced in accordance to the vendor's recommendation for preventive maintenance)
- Vaccination providers must also ensure that a **suitably qualified doctor or nurse is available for the assessment and management of emergencies (e.g. anaphylaxis)** in accordance with MOH's guidelines

\*The emergency drugs and facilities required are Adrenaline, Hydrocortisone, Antihistamine, IV drip set, IV cannula, IV fluids, manual bag valve resuscitator and oropharyngeal airway (at least of two different sizes). Optional resuscitation facilities may include the bronchodilator, pulse oximeter, oxygen, intubation kit, and defibrillator/automated external defibrillator.

### MOH's guidelines on management of anaphylaxis and severe allergic reactions



MINISTRY OF HEALTH  
SINGAPORE

MH 34:24/8 MOH Circular No. 30/2021

15 March 2021

All Medical Practitioners

**REVISED GUIDELINES ON THE MANAGEMENT OF ANAPHYLAXIS AND SEVERE ALLERGIC REACTIONS AFTER COVID-19 VACCINATION IN ADULTS**

This Circular sets out the revised guidelines on the management of anaphylaxis after COVID-19 vaccination in adults and supersedes MOH Circular No. 19/2021 with immediate effect. Amendments are **italicised and highlighted**.

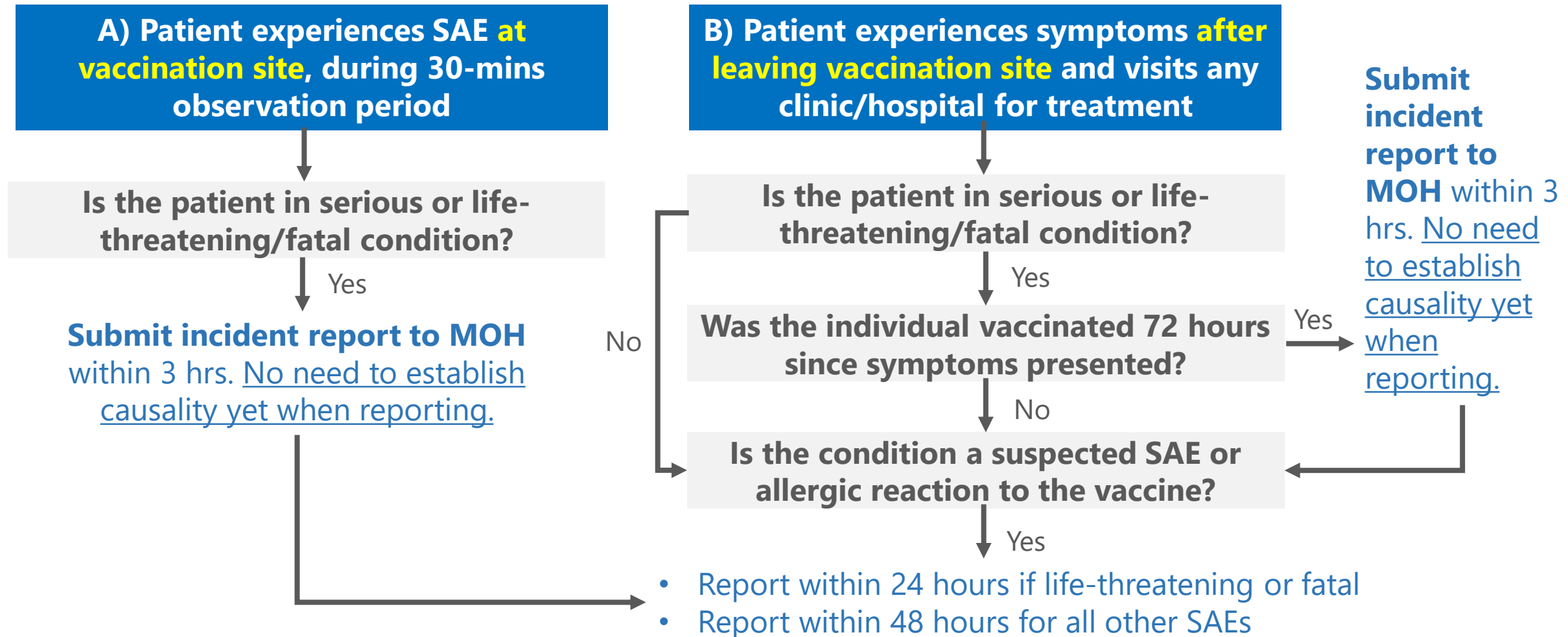
Anaphylactic reactions to vaccines (including COVID-19 vaccines) are rare but potentially life-threatening. These immunoglobulin E (IgE)-mediated reactions are commonly due to vaccine constituents as opposed to microbial products. Under-recognition of anaphylaxis is common, hence rapid identification is vital. These guidelines inform all medical practitioners on the recognition and management of anaphylaxis and severe allergic reactions post-vaccination.

**RECOGNITION OF ANAPHYLAXIS**

- All persons who receive COVID-19 vaccines have to be seated and should be observed for 30 minutes after vaccination<sup>1,2</sup>. When anaphylaxis occurs after the administration of vaccine, patients generally develop symptoms within 30 minutes, although the onset may rarely be delayed for up to several hours.
- Medical practitioners are advised to provide treatment for anaphylaxis in patients with **two out of three** of the following **sets of symptoms**:
  - Acute onset mucocutaneous symptoms** (flushing, pruritus, urticaria, angioedema - look out especially for swelling of lips, tongue and uvula);
  - Respiratory symptoms and signs** (wheezing, stridor, hypoxia, shortness of breath, sensation of throat tightness and hoarse voice);
  - Symptoms and signs of hypotension** (fainting, dizziness, confusion, a drop in systolic blood pressure (BP) to <90mmHg or diastolic blood pressure <60mmHg within minutes to several hours post-vaccination);

<sup>1</sup> The Center for Disease Control (CDC), United States, found that 71% of persons who experienced anaphylaxis showed symptoms within 15 minutes post-vaccine administration.  
<sup>2</sup> Closer monitoring (of up to an hour) may be warranted for the elderly. Check blood pressure and ensure that they are well before discharge.

**04** For vaccine safety monitoring and situational awareness, MOH and HSA require healthcare professionals to report any Serious Adverse Events (SAE) within specified timeframes and via designated systems



## 04 From 30 Dec 20 to 18 Apr 21, 0.004% of vaccine doses administered have been accompanied with a suspected SAE report

- The Pfizer-BioNTech COVID-19 vaccine was rolled out for use on 30 December 2020, followed by the Moderna COVID-19 vaccine on 12 March 2021
- As Pfizer-BioNTech vaccine comprised 92% of the doses administered in our population, most of the AEs reported were associated with the Pfizer-BioNTech COVID-19 vaccine
- Based on a total of about 2.2 million doses of the vaccines administered, HSA received 2,796 suspected AE reports (**0.13% of doses administered**)

	COVID-19 Vaccines (Pfizer-BioNTech and Moderna)
No. of persons who have received first dose	1,364,124
No. of persons who completed full vaccination regimen*	849,764
No. of doses administered	2,213,888
No. of suspected AE reports	2,796 ( <b>0.13%</b> of doses administered)
- No. of suspected serious AE reports	95 ( <b>0.004%</b> of doses administered)

\* The full vaccination regimen for Pfizer-BioNTech and Moderna COVID-19 vaccines comprises 2 doses.  
All rights reserved, Health Sciences Authority

# Vaccination Certificates


Those who have completed their vaccination regime will receive a physical vaccination card and can access their vaccination status via apps which can exempt them from pre-event testing in local settings

## 1. Vaccination Card

**Information about COVID-19 Vaccination**

The COVID-19 vaccine you have received consists of two doses. The second dose must be completed to achieve the best possible protection, and for the protection to be as long-lasting as possible.

The vaccine has been assessed to be safe for use. However, just like other vaccines, you may experience some side effects such as headache, body aches, tiredness and soreness at the injection site, or fever. These usually get better after 1-3 days and may be a sign that your immune system is making a protective response against COVID-19.



MINISTRY OF HEALTH  
SINGAPORE

**COVID-19 VACCINATION CARD**  
Please bring this card for your next appointment

**PERSONAL PARTICULARS**

Name: \_\_\_\_\_

NRIC/IN: \_\_\_\_\_

DOR: \_\_\_\_\_

Your Next Vaccination is Due In _____ Days			
Appointment Date	Time	Place	

COVID-19 Vaccination Record			
Vaccine Dose	Date of Vaccination	Vaccine Brand	Place of Vaccination
<input type="checkbox"/> #1		<input type="checkbox"/> Pfizer-BioNTech <input type="checkbox"/> Moderna <input type="checkbox"/> Sinovac <input type="checkbox"/> Other: _____	
<input type="checkbox"/> #2		<input type="checkbox"/> Pfizer-BioNTech <input type="checkbox"/> Moderna <input type="checkbox"/> Sinovac <input type="checkbox"/> Other: _____	


  

After Vaccination Advice	
Possible Side Effects	How to Manage
Pain, redness, swelling at the injection site	Paracetamol 1 to 2 tablets every 6 hours as needed
Fever, chills	
Headache, muscle pain, joint pain	
Tiredness	
Lymph node swelling at neck or arms	
See a doctor if:	
<ul style="list-style-type: none"> <li>the side effects persist or get worse</li> <li>the fever persists for more than 48 hours (2 days)</li> </ul>	

This vaccine may cause a severe allergic reaction in very rare instances.  
If you experience a severe allergic reaction, seek immediate medical attention by calling 995 or going to the nearest A&E.


## 2. TraceTogether

📶 1-5 devices nearby
4 mins ago




**Your COVID Health Status** N/A

Vaccinated




No exposure alerts




COVID test result

Coming Soon


**SafeEntry check in**



Scan QR



Favourites



Group


Stay safe together.  
Share the app!

[Create TraceTogether](#)

Home
History
Upload
More

## 3. HealthHub

**Vaccination Records**



**Vaccination in Progress**

Please wait 14 days after final dose for the vaccine to take effect.


**COVID-19 PFIZER-BIONTECH (A-COV)**

[Less details](#)

**19 JAN 2021**

**Dose: D1**

BATCH NO.: EK4245  
FAMILY CARE CLINIC PTE LTD

 [Download PDF](#)

# Vaccination Certificates

## For overseas settings, MOH also issues vaccination certificates for those who are vaccinated locally and require proof for travel

- The process for requesting and receiving the digital vaccination certificate is similar to the request for endorsement of digital pre-departure certificates
- The digital vaccination certificate is available at the Government Notarise website and is currently tagged to the individual's passport number
- <https://www.notarise.gov.sg/>

### VACCINATION CERTIFICATE

**Name of Person:**

**NRIC/FIN Number:**

**Passport/Travel Document Number:**

**Nationality/Citizenship:**  
Singaporean

**Date of Birth:**

### Dose 1:

**Manufacturer/Vaccination Name/Brand/Type:**  
PFIZER-BIONTECH COVID-19 Vaccine  
[Tozinameran] Injection

**Clinic/Vaccination Centre:**  
Vaccination site approved by Ministry of Health (MOH),

**Date of Vaccination:**  
8 February 2021

**Batch Number:**  
EK4245

**Country of Vaccination:**  
Singapore

**Health Worker:**  
Designated vaccinator by MOH-approved vaccination site

### Request Vaccination HealthCert



Select vaccination for issuance.

REQUESTED

NAME



PFIZER-BIONTECH COVID-19 Vaccine [Tozinameran] Injection

Completed Vaccination Date: 2021-03-02