# *Temporary suspension of Flu vaccination –* Lessons FPs should learn

by Dr Leong Choon Kit, FCFP(S)

"2 flu vaccines linked to deaths in South Korea should be 'temporarily ceased': MOH"  $^{\rm 1}$ 

"Use of two flu vaccines should stop temporarily after deaths in South Korea: MOH"  $^{\rm 2}$ 

The news first broke out on the 25<sup>th</sup> October 2020, six days before the launch of the Ministry of Health Vaccination Subsidies Program (VSP).

First thing on my mind was not whether the news is true. It has never crossed my mind that this would ever happen to a tried and tested vaccine.

The influenza vaccine is most likely the most administered vaccine in terms of frequency and volume. Given that kind of volume, the rate of adverse events from the influenza vaccine has been few and far in between.

In fact, many studies have shown that the complication rate from the naturally acquired infection is far higher than that from the vaccine.<sup>3</sup>

#### Impact of the News

My concern after reading the headings was the impact it has on the going to be launched Vaccination Subsidies Program (VSP).

Over the next few days, my fear was proven right. My patients started to question about the safety profile of all vaccines. Not just that of the Influenza vaccine, not even the specific brands.

In our private GP WhatsApp group chat, some of our colleagues are starting to doubt the safety and usefulness of vaccination.They are worried about the backlash by their patients should they push hard for the VSP. I can sense that our colleagues are even losing self confidence in advocating any vaccine.

### **Gathering information**

The next thing I did was to look for more information. I started contacting all my contacts working in the various pharmaceutical companies which manufacture vaccines. I also contacted my medical mission counterparts in Korea and seek more information.

### Press Release from Korea CDC

As a background, it is imperative to know and understand how the flu vaccination program works in South Korea. "The Korean influenza national immunization program was first established as an interim program in 1997, administering the influenza vaccine to low-income elderly adults. In 2005, the program assumed its present form of providing free influenza vaccination to adults aged  $\geq 65$ years. ... in 2015, the influenza vaccination coverage rate among this population increased to > 80%..... By reaching a 75% vaccination coverage rate in the target groups, it was possible to put an end to the influenza pandemic ..." <sup>4</sup>

#### Interpretation

South Korea has a national influenza vaccination program reaching past 80% coverage of their population. Based on the latest census done in 2018, South Korea population is 51.64 million. In other words, 41 million South Koreans would have received the Influenza vaccine.

At the time of the news on the 25<sup>th</sup> October 2020, it was reported that there were 48 deaths reported by medical practitioners as part of their adverse reaction surveillance system. This works out to be 0.00011707%.

According to US CDC report for 2018-2019, among the 35.5 million people who contracted influenza naturally, 34,200 died. This data works out a case fatality rate of 0.096%.  $^5$ 

Even if the death in South Korea is really related to the vaccination, the case fatality rate between the vaccine and the natural disease is clearly significantly less.

Examining the press release  $^{6}$  by the South Korean authority further, it revealed that 41 out of 48 of them are above 70 years old. There was almost equal distribution between the two gender.

Autopsies were performed and completed among twenty of the deaths at the time of the press conference. Thirteen of them died of cardiovascular causes. None of them were related to anaphylaxis secondary to administering the vaccination.

Another interesting point to note in the statistics that were released was the geographical distribution of these deaths. The deaths occurred almost evenly in 14 out of the 17 provinces, ranging between one to six deaths in each province.

(continued on the next page)

(continued from Page 19: Temporary suspension of flu vaccination - Lessons FP should learn)

The medical facilities used 7 different brands of flu vaccines in South Korea and the number of deaths were also distributed more or less equally among the brands.

Examining these data show that it is not brand specific, not district specific and there seems not to be any correlation between the deaths and the vaccine.

However, it is noted that there was mentioned about some white particles floating in some flu vaccines. This was later rectified and found to have no safety concerns.

**Beyond South Korea** 

Looking beyond South Korea, we should note that this entire phenomenon was not seen anywhere else in the world. This is despite that some of these brands are also used in other countries. For instance, Singapore uses two of the brands, namely SKYCellflu Quadrivalent and Sanofi's Vaxigrip Tetra.

"Doctors in S'pore who gave vaccine linked to South Korean deaths say no patients

have reported complications" <sup>7</sup> Other than the usual side effects associated to most vaccination which resolved spontaneously, there were no major adverse reactions reported locally.

#### Modern Healthcare system

The modern healthcare system is evidence based and grounded in science and physiology.

It is a system that makes medicine and treatment safe. Understanding how each medicine or biologics like vaccine is studied, undergo trial and implemented will help one gain confidence in the healthcare system we practise in.

Added to the safety is the transparency of the modern healthcare system as well as the speed of transferring and sharing information in this internet connected world.

Data are shared openly, freely and quickly. Analysis can then be done worldwide at the first instance when trouble or suspicion of trouble is identified.

After a therapeutic has passed through phase III trial, there is still a system of post market surveillance which some will call it Phase IV trial. It is this post market survey that picks up the 48 deaths.  $^8$ 

| In the modern healthcare system, we always err on the side   |
|--|
| of caution. That makes our system safe. For the uninitiated, |
| they may feel that the system is dangerous. As doctors, we   |
| need to be know this very well so as to help the public      |
| understand.  |

In addition, we should also be watchful of any potential adverse events or effects post vaccination and report these to our local equivalent which is the Health Science Authority (HSA). The Family Physicians and General Practitioners are all part of this safe healthcare system we have created.

# Response is always illogical

The public response to such sensational news is always irrational and exaggerated. This is understandable. The main reason is because the vaccine involves one's body and life. Besides, vaccination is a preventive measure and is seen largely as elective by the public.

It is hard to expect the public to understand that the risk of contracting and dying from an influenza

infection when there was no outbreak. In fact, the current Covid19 pandemic has distracted many to focus ons the Covid19 virus and largely ignore all other outbreaks such as influenza and dengue.

#### Importance of Influenza vaccination in the current Covid19 Pandemic

It is very important to protect the elderlies and the immunosuppressed among us this season. Having vaccinated against influenza will reduce the noise of diagnosis during the Covid 19 outbreak.<sup>9</sup>

Covid19, influenza, pneumococcal and other infections are not mutually exclusive. There were reports that in some centres such as the emergency department at Stanford, it was observed that 21% of those who were tested positive with Covid19 had concurrent other respiratory viruses infection.

From a physiological point, the risk of dying is much higher when one contracts more than one infection concurrently. This would be particularly so if the patient also suffers from chronic diseases  $^{10}\,$ 

Dec 2020 VOL 46(4)



SUMMARY OF INFLUENZA VACCINE SCARE IN

SOUTH KOREA 2020

(when the news first broke on 25<sup>th</sup> Oct 2020)

48 deaths occurred throughout

Almost all the deaths were

among those above 60 years old

Some of the vaccines were found

with the majority in their 80's

to have white particles which

were confirmed to be safe but

removed from use.

the 17 provinces

South Korea has a nationalized

influenza vaccination program

Majority of the deaths were

associated with cardiovascular

7 different brands were used and

the death were evenly distributed

with high uptake

among the brands

conditions

# Family Physician / General Practitioner's role

As Family Physicians, our patients will look towards us for guidance and advice. It is also important for us as clinicians

to adhere strictly to MOH directives. Thus, we have to be careful to convey the correct message to our patients.

In that case, it becomes apparent and important for FP / GPs to take the initiative to search for answers. FP / GPs should also use our training in basic sciences and research methods to understand the facts placed in front of us.

When we the Family Physicians / General Practitioners are clear about the issues, we will lend confidence to the vaccine and the public when vaccination is resumed.

In the days of antivaxxers hiding and masking themselves behind many healthcare articles and websites, the job to advocate for a good vaccination

program is made that much more difficult and challenging.

The job of the doctors would then be the guiding light. Therefore we need to be well versed with the most updated information. The General Practice today is also made more difficult by the many new aspects of medicine we are required to be familiar. It is almost impossible for a single GP to know enough breadth and depth of medicine.

Hence, we must learn to divide and conquer the fields of medicine. Family Physicians must come together and take on the role of specialists in their respective areas of interests. That way, we will be able to help guide our fellow GPs and the junior FPs along.

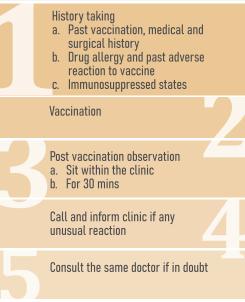
Ultimately, the more unified the discipline of Family Medicine, the healthier our population.

# Suggested vaccination protocol Consultation before vaccination

Before administering any vaccine, it is important to have a detailed and properly conducted and unrushed consultation.<sup>11</sup> The vaccines advised should be customised to the risk factors faced by the recipients.

A detailed history is needed to be taken and it must include but not limited to past history of medical and surgical history, any adverse events or allergies post vaccination and any conditions or therapies that may suppress the recipient's immunity. The public may not be aware that immunosuppressed states like HIV, poorly controlled diabetes mellitus, those who have recently completed chemotherapy as well as those on immunosuppressive therapies after organ transplant or

# Suggested protocol for VACCINATION IN PRIMARY CARE



treating autoimmune diseases are contraindicated.

During the consultation, the physician should also answer any queries that the recipient may have and addressed their concerns. If the recipient is in doubt, it is advisable to postpone the vaccination.

After administering the vaccine, it is also important to look out for immediate post vaccination reaction. This can range from the mild reaction in the injection site to pain, fainting spells caused by vaso-vagal reaction to severe anaphylaxis.

With that in mind, it would be wiser to keep the recipient in the clinic for at least half an hour after vaccinating. That would also mean that patients

requiring vaccination should not be seen too close to clinic closing hours.

It is important to advise the recipient to return to the clinic should they feel unwell or experience any signs and symptoms post vaccination.

With a proper protocol in place, it will ensure safety and build confidence among our public and our patients.

- Reference
- <sup>1</sup> Justin Ong, Today 25th Oct 2020
- <sup>2</sup> Audrey Tan, The Straits Times 26th Oct 2020
- <sup>3</sup> Evaluating the safety of influenza vaccine using a claims-based health system. Natalie L McCarthy et al. Vaccine. Volume 31 Issue 50 December 2013 Pages 5975-5982
- <sup>4</sup> The Korean Influenza National Immunization Program: History and Present Status. Jae-Won Yun et al. Infection Chemotherapy. 2017 Dec; 49(4): 247–254
- <sup>5</sup> Influenza US CDC website
- <sup>6</sup> Follow precautions for safe influenza vaccination. Press release, Vaccination Management Division, Korea Centers for Disease Control. 24th Oct 2020
- <sup>7</sup> Nabilah Awang, Tan Yin Lin. Today 27th Oct 2020
- <sup>8</sup> Clinical trials -FDA Website. About Clinical Trials WCG CenterWatch
- <sup>9</sup> Influenza immunisation and COVID-19. Helena C Maltezou et al.Vaccine 38 (2020) 6078-6079
- <sup>10</sup> Predictors of mortality for patients with COVID-19 pneumonia caused by SARS-CoV-2: a prospective cohort study. Rong-Hui Du et al. European Respiratory Journal. 2020 May; 55(5): 2000524
- $^{11}\,\rm Vaccine$  administration protocol US CDC website



