FACT VS. FALLACY: A Response on the Issues Raised Against COVID-19 Vaccination in Children

On 2 November 2021, the Centers for Disease Control and Prevention (CDC) recommended COVID-19 vaccination in children, ages 5-11 in the United States. The European Union followed suit and began their vaccination rollout for this age group last 13 December 2021. Since then, approximately 8.7 million doses in children aged 5-11 years have been given in the US and even more across the globe.

In the Philippines, the Department of Health (DOH) recommended the vaccination of children ages 12-17 with COVID-19 mRNA vaccines, granted Emergency Use Authorization (EUA) by the Food and Drugs Administration (FDA). The rollout started on 15 October 2021 (see DOH Department Circular 2021-0464).

On 22 December 2021, the Philippine FDA issued an EUA for a new formulation of the Pfizer COVID-19 vaccine (Cominarty) containing a lower dose (10 mcg) for use in children aged 5 -11 years. The DOH plans to roll out vaccination using this lower dose formulation in children ages 5 to 11 beginning this 7 February 2022. In the advent of this rollout, spread of misinformation and concerns are being raised regarding covid vaccines and the need for vaccinating children.

This paper seeks to clarify and shed light on some of the issues and concerns raised.

Claim No. 1: There are serious safety concerns with the mRNA vaccines

FACT CHECK:

The CDC released a COVID-19 vaccine safety report in children aged 5-11 years (Hause, *et al.*, 2021). Using the Vaccine Adverse Event Reporting System (VAERS), they have found that 97.6% of the reports mostly consisted of local side effects such as injection site redness, fever, or headache which did not interfere with normal daily activities.

There are social media claims that COVID-19 vaccines may cause damage to children's health. Published data shows that COVID-19 vaccines help in reducing the risk in two forms: (1) developing severe COVID-19 and (2) having symptomatic disease

A recently published study by the CDC last 14 January 2022 (Zambrano *et al.*, 2022) has shown that the Pfizer Covid-19 vaccine (an mRNA vaccine) was highly effective

at preventing Multisystem Inflammatory Syndrome in Children (MIS-C), a serious complication from COVID-19.

Out of all 8 million vaccine doses, there were only 11 verified adverse event reports of myocarditis among children aged 5-11, according to the CDC report. These cases were mild and self-limiting without the need for any major therapeutic intervention compared with myocarditis among patients with severe COVID-19. Unvaccinated individuals infected with COVID-19 had 16 times the risk of myocarditis (Boehmer, *et al.*, 2021) compared to vaccinated people.

KEY POINT: ***Vaccinating your child decreases their risk of having severe COVID-19 and its complications. The protection that COVID-19 vaccines offer outweigh the risk of developing mild, self-limiting adverse events****.*

Claim No. 2: COVID-19 vaccines are experimental and unsafe as they were made in "warp speed"

FACT CHECK:

It might seem surprising that the new COVID-19 vaccines were developed at a faster rate. Keep in mind, however, that the established system of vaccine development *did not change*. In other words, the expedience in which these life-saving vaccines were developed did not sacrifice safety, as safety has *always* been its top priority.

In the timeline of COVID-19 vaccine development, we must keep in mind these five (5) points adapted from Barnes-Jewish/Christian (BJC) HealthCare:

1. *We already had a head start.* While the intention of creating vaccines against COVID-19 is new, the technology used to create such vaccines is not unfamiliar. In fact, development has derived its strategy from working on the original SARS (severe acute respiratory syndrome, 2003) and MERS (Middle-East respiratory syndrome, 2012) virus outbreaks. It is therefore not surprising that a huge portion of starting the COVID-19 vaccine development has been laid out already – giving the whole process a seemingly faster progress.
2. *No short-cuts were taken*. Because the goal of scientists, doctors, regulatory bodies, and ethics committees lies in saving lives through vaccination, they were able to execute all required steps in parallel – saving time yet not compromising (or skipping) any of the steps.
3. *Careful testing was done under rigorous standards.* The FDA always sets standards for all vaccine developers. They must meet these strict requirements prior to an approval. All clinical trial data were carefully reviewed before any approval was granted, to ensure that *safety* will always be the top priority.

4. *Emergency use authorization was granted during the pandemic.* If there is an emergency, which often entails a life-or-death situation, one must act quickly to respond but always with the best intentions in mind. After due diligence and thorough review of all available data, the FDA granted Emergency Use Authorization (EUA) for COVID-19 vaccines that are BOTH safe AND effective. Approved vaccines granted EUA by various regulatory agencies have demonstrated clear benefits that outweighed the risks.
5. *Problems and side effects are actively monitored*. For every vaccine approval, there is always an ongoing safety evaluation post-approval. Systems are always in place to monitor these problems to continuously provide insight to regulatory authorities, public health departments, and the general public. Always remember, safety will always be the top priority.

KEY POINT: ***The established system of vaccine development has always placed safety as its top priority. Even with a head start, no steps were skipped, and systems for monitoring are always in place.***

Claim No. 3: COVID-19 infection in children is just mild like the flu and there is no benefit in vaccinating them

FACT CHECK:

Getting COVID-19 carries a risk that children may become very unwell. There is also a potential to develop post-COVID-19 symptoms and/or severe complications (such as MIS-C). Naturally infected children can also spread the virus to others. Vaccination can significantly reduce the risk and protect children from developing COVID-19 in a safe and controlled way. It can also reduce the chance of spreading the virus to others.

Although MIS-C is a rare condition, its incidence is highest in the 5-11 years old age group. The CDC COVID-19 tracker showed that 45% percent of MIS-C cases in the US fall under this age group. Vaccine trials in this age group also show that vaccination prevented 90% of symptomatic COVID-19 infection.

KEY POINT: ***Regardless of the expected severity of illness in children, vaccination can protect children from experiencing severe forms of the illness and life-threatening conditions caused by COVID-19 such as Multisystem Inflammatory Syndrome in Children (MIS-C).***

Claim No. 4 : There are excess deaths coinciding with the roll out of vaccination

FACT CHECK:

This is a perfect example that can illustrate the phrase “correlation does not imply causation.” Basing solely on the observed association of excess deaths and vaccine rollout does NOT establish a legitimate cause-and-effect relationship. Data cannot simply be juxtaposed and then imply a conclusion. There are many reasons for these deaths that it will be irresponsible to deduce that such an effect was caused by vaccines.

KEY POINT: ***There is no proof that cause of excess deaths is due to vaccine rollout.***

Claim No. 5: Infection-induced (natural immunity) is better than vaccine-induced immunity

FACT CHECK:

Both natural infection and vaccine will induce immunity which will wane overtime. However, natural infection can lead to serious disease, complications, and death. Vaccination affords protection without getting sick with the virus.

The subsequent course of natural COVID-19 infection is unpredictable while the risk associated with vaccination is minimal. Even if natural infection occurs, subsequent COVID-19 vaccination will enhance the protection against the disease.

KEY POINT: ***COVID-19 vaccination protects against the disease.***

Claim No. 6: The risk of dying from serious complications of the vaccines that will appear later on is equal or higher than the risk of dying from COVID-19 today

FACT CHECK:

To date, there is no evidence linking mRNA vaccines as a direct causation to patient death. Health care providers are required to report any death after COVID-19 vaccination even if the reason of causality was unclear. According to CDC data, more than 539 million COVID-19 vaccine doses have been administered by January 2022. Among those who received a COVID-19 vaccine, only 11,879 preliminary reports of death (0.0022%) were received. Continued monitoring has not identified causal association between the Pfizer COVID-19 vaccine and these deaths.
In the Philippines, out of the 8.8 million doses administered in the adolescent population, there is no death directly caused by administration of Covid vaccine.

KEY POINT: ***There is no causality between mRNA COVID-19 vaccination and deaths–which cannot be measured against risk of dying from COVID-19 and its complication.***

Claim No. 7: Vaccinated people are superspreaders

There is the notion that since vaccinated individuals have less symptoms or are asymptomatic, they can spread the disease without them knowing, making them super-spreaders.

FACT CHECK:

Vaccines not only prevent severe COVID-19, but they may also decrease viral transmission as shown in emerging data from studies. Vaccines prevent infections (and hence transmission) and vaccinated individuals clear infections quicker and have a more rapid decline in viral load (Chia, *et al.*, 2021; Micochova, *et al.*, 2021).

KEY POINT: ***Emerging data support that vaccination against Covid-19 may decrease viral transmission. There is no evidence to support that vaccinated people are super-spreaders of COVID-19.***

Claim No. 8: mRNA vaccines stay in the body and invade organs for a longer period of time

FACT CHECK:

This claim is purely speculative at best, as there is no evidence supporting this idea. The vaccine will be broken down by body processes once it has initiated the immune response. mRNA is fragile and destroyed shortly after entry in the cell. It cannot enter the nucleus and integrate with the host DNA, cause genetic abnormalities, afftect reproduction,etc. They may stay in the body for a few weeks but unlikely an extended period of time.

KEY POINT: **There is no evidence that mRNA vaccines persist in the body and invade organs.**

Claim No. 9: The COVID-19 vaccine has a heart attack-stopping ingredient tromethamine to counter myocarditis

Is it true that manufacturers replaced the saline buffer in the vaccine with a medication called tromethamine to counter the myocarditis side effect?

FACT CHECK:

While it is true that the new vaccine formulation used in children involves the replacement of the saline solution with tromethamine, the reason is actually geared towards stabilization of the vaccine's pH for longer periods of time.

Tromethamine, also known as Tris buffers, is an FDA-approved buffer commonly used in other vaccines, including those used for children. Tromethamine is not a medication used for heart inflammation, but it is used for stabilizing the pH (acidity and alkalinity) of the vaccine. In this way, the vaccine can be stored at appropriate temperatures for a longer period of time.

KEY POINT: ***Tromethamine is not a heart medication but functions as a stabilizer so that the vaccine can be stored for a longer period of time.***

Claim No. 10: Unvaccinated individuals get sick because vaccinated individuals shed spike proteins

FACT CHECK:

CDC noted that "vaccine shedding" is the term used to describe the release or discharge of any of the vaccine components in or outside of the body. Vaccine shedding can only occur when a vaccine contains a weakened version of the live virus. At present, *none* of the authorized vaccines in the country (or globally for that matter) contain live virus.

While viral shedding can be observed in individuals with COVID-19, there is simply no evidence that spike proteins from vaccines can be shed by a vaccinated person.

KEY POINT: ***Viral shedding can be observed with individuals naturally infected with COVID-19. There is no evidence that vaccinated individuals can shed the spike proteins.***

Claim No. 11: We do not need vaccines anymore since the dominant variant is Omicron that has multiple mutations and it evades vaccine immunity

FACT CHECK:

It is true that the Omicron variant is unique with its high transmissibility and its ability to evade vaccine-induced immunity with its 50 genetic mutations. However, (1) natural immunity from the Omicron variant does not last long; and (2) mild Omicron infection does not induce strong immunity. Therefore, unvaccinated children are at risk for multiple re-infections, and with every infection carries a risk of developing severe disease. Vaccination protects children from developing severe forms of the disease as well as associated complications such as MIS-C.

Although mRNA vaccines are less effective towards Omicron compared to other variants (70 percent protection against hospitalization and 33 percent protection against Omicron infection), recent studies show that a full vaccination series plus a booster provides significant protection from severe disease (protection against infection rises to around 75 percent, and 80 to 90 percent for severe disease). As we have no way of knowing if an infected child's illness will progress to severe COVID, having your child vaccinated decreases their chance of developing a more serious

disease or any of its complications. Additionally, experts would even argue that the currently observed “mildness” of the Omicron variant illness may be due to the pre-existing population immunity. In simple terms, people with pre-existing immunity against COVID-19 infection through vaccination are expected to have less severe outcomes from any subsequent infection.

KEY POINT: ***Unvaccinated children are at-risk of getting COVID-19 and potentially be reinfected, with every infection carrying a risk of developing severe disease. Vaccinating your child decreases their chance of getting this serious condition.***

Moving Forward

COVID-19 has reshaped the way we live, encouraging the advancement of science and technology. With the collective efforts of scientists all over the world, effective, innovative and safe vaccines were developed to prevent further loss of lives from this virus. Unfortunately, disinformation and misinformation from misguided individuals have undermined the efforts of the medical and scientific community in putting an end to this pandemic. The dangers of spreading these falsehoods may not only result in sowing distrust in the scientific community and the public, but may even result in unintended deaths. It is within our right to question any mandate, especially if life and liberty is compromised, but this should be based on truth and should be expressed responsibly.

Vaccination using age-appropriate COVID-19 vaccines is the way forward toward reducing COVID-19 disease and deaths and ending this pandemic.

“From principles is derived probability, but truth or certainty is obtained only from facts.”
Attributed to ***Tom Stoppard***

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