Introduction

The development of modern vaccines and subsequent vaccination aimed to prevent thousands of illnesses and deaths during a pandemic and can be regarded as one of the greatest public health achievements [1]. Vaccines play a critical role in preventing hospitalization and deaths caused by infectious diseases or pandemic outbreaks. Since the emergence of the coronavirus disease 2019 (COVID-19) pandemic and its global impacts, there has been an unprecedented level of public interest in vaccine development and safety monitoring [2]. Although the disabilities from a vaccine-preventable disease are far worse than a vaccine itself, it appears there is increased refusal of vaccination due to these safety concerns [3]. Unverified reports of adverse events following COVID-19 vaccination have been a key source of concern, and there are dubious claims that the vaccine is potentially more dangerous than acknowledged [4].

The multi-state measles outbreak in the United States between 2014 and 2015 was met with unsubstantiated claims of deaths caused by the measles, mumps, and rubella vaccines (MMR) [5,6].
sarily caused by a vaccine or related health problems. VAERS cannot determine whether a vaccine is responsible for the adverse event, but rather the adverse event occurred sometime after the vaccination [7]. While essential to monitor vaccine safety, the VAERS alone cannot be used as proof for adverse events.

It is a passive surveillance system and reports may contain information that is incomplete, coincidental, and inaccurate and unverified [8]. In this paper, we conducted a literature search and summarized available information and published epidemiological data on deaths following the COVID-19 vaccination. The review includes adverse events where there is reasonable scientific evidence to conclude that vaccination campaigns caused or did not the death. This summary is restricted to deaths related to COVID-19 vaccination and does not involve instances of human factors or medical errors.

**Historical Vaccine Safety Concerns**

Following the 200th anniversary of Edward Jenner’s first smallpox vaccination, the subsequent development of vaccines continued to have safety concerns among the general population. Despite the existence of solid and scientific evidence that the benefits of vaccines outweigh the risk, public opinions, deep-seated beliefs, and divergent cultural viewpoints have taken a stance toward vaccination. The first high-profile past vaccine safety concern was the Cutter incident in 1955 American polio vaccine program which led to the vaccine crisis. In this program, more than 200,000 children received a polio vaccine containing the live poliovirus [9]. The vaccines were detected with reports of paralysis within a month of the first vaccination, and the campaign was abandoned [9]. The Cutter incident later on thorough investigation caused 40,000 cases of polio, leaving 200 children with paralysis while killing 10 [10]. The Cutter incident, a defining moment in the history of vaccine development, is attributed to the California-based company Cutter Laboratories. After the Cutter incident, the US government created a better system of regulating and increasing the oversight of vaccines.

Afterwards (from 1955–1963), estimates showed 10%–30% of the polio vaccines administered were contaminated with simian virus (SV40) which originated from monkey kidney cells used to culture the polio vaccines at that time [9]. The concerns of simian virus causing cancer in humans were high, but research found no causal association between SV40 contaminated polio vaccine and the development of cancer [11] and no vaccine contain the simian virus today.

In 1976, scientists found a small, increased risk of a neurological disorder known as the Guillain-Barré syndrome (GBS) with the swine flu vaccines. The risk was small, with approximately one additional case of GBS for every 100,000 people following swine flu vaccination resulting in 53 deaths [9]. Federal authorities abruptly stopped the vaccination program after 40 million people were vaccinated against the swine flu. The institute of medicine through a scientific review issued in 2003 concluded that individuals who received the 1976 swine influenza vaccines had an increased risk of developing GBS. In the late 1990s, hepatitis B vaccination was linked with the progressive neurologic disease of multiple sclerosis. The first vaccine developed to prevent rotavirus gastroenteritis caused intussusception in some infants.

A more recent controversy that happened in the 2000s includes the GBS and meningococcal vaccine (2005–2008) where a number of youths reported GBS after receiving Menactra, the Haemophilus influenzae type B vaccine recall in 2007 due to contamination with a bacteria called Bacillus cereus, the H1NI influenza vaccines, and narcolepsy (2009–2010), the porcine circovirus in rotavirus (2010), and the immediate past (2013) recall of Gardasil human papillomavirus due to precaution error in manufacturing processes with no health problems presented. The decades of history reviewed above show that vaccines have had an impact on human health over the last 40–50 years. There are unexpected incidences (bad outcomes) related to the process of making them, some people have distrust in vaccines and others will not be ready to take them when they are finally rolled-out [12].

It is equally considerable that the very successful vaccine to date has met a significantly growing number of anti-vaccination sentiments. Post-vaccination COVID-19 fatalities are not taken out of context and there are some levels of vaccine failure associated with every vaccine which the COVID-19 vaccine is not an exception [12] (Table 1).

**Current Epidemiological Data on Deaths Associated with COVID-19 Vaccination**

The Centers for Disease Control and Prevention (CDC) has admitted and confirmed an increased number of fatalities following the COVID-19 vaccination [13]. The European Medicines Agency (EMA) has equally published a safety update on available deaths cases since authorizing the COVID-19 vaccines.
The death toll from the COVID-19 vaccine is greater than every vaccine in the last 20 years combined [15]. The number of deaths received by the VAERS from other vaccines is lower compared to the authorization of the COVID-19 shots [15]. Around the world, all eyes are on the distribution and outcomes of the COVID-19 vaccine. This implied that data, results and ongoing studies concerning the effectiveness and safety of the vaccine are consistently available and analyzed. The CDC from December 14, 2020, to July 19, 2021, through the VAERS, recorded 12,313 reported deaths among people who have received the jabs [13]. As of July 4, 2021, the EMA issue safety update including deaths related to four of its authorized vaccines namely Spikevax, Vaxzevria, Comirnaty, and COVID-19 vaccine Janssen [14] (Table 2).

After careful review of the reports, there is no enough evidence that the COVID-19 vaccine contributed to those fatalities [16]. Clinical information such as death certificates, autopsy, and medical records establish no causal link to the COVID-19 vaccines according to the CDC. The death of a person following vaccination does not necessarily mean, the vaccine caused health problems and could be coincidental. Research done by the Paul Ehrlich Institute (the body in charge of vaccines in Germany) stated that patients died of their underlying diseases in a coincidental time with vaccination. This came after 10 COVID-19 vaccination deaths were recorded in the country [17]. Early studies conducted by the Norwegian Medicine Agency on reports of 33 deaths in a nursing home following vaccination of residents’ revealed death occurred close to these terminally ill patients at the time of vaccination [17]. It does not imply a causal relation to the vaccine [17].

In a review done by European Medicines Agency’s Pharmacovigilance Risk Assessment Committee, it is conceivable that pre-existing diseases seemed to be a plausible explanation for COVID-19 vaccination deaths [17]. Moreover, the Spanish media reported nine deaths in a Spanish care home after receiving the first dose of the Pfizer-BioNTech jab, all of whom had underlying conditions [17]. On the other hand,
there have been instances where deaths were due to the COVID-19 vaccines. On June 17, Michigan health authorities reported to the CDC that a 13-year boy died 3 days after receiving the second dose of the same jabs [18]. A 39-year-old Alabamian woman with no underlying condition also died 4 days after receiving the second dose of the Moderna vaccine [19]. According to reports she experienced no major side effects after the first dose except for a sore arm [19]. In a related development, an Orange County health worker aged 60 years on January 9 died after receiving the second dose of Pfizer’s coronavirus vaccine [20]. In an investigative study, three persons died, and it appeared to be linked to blood clots that occurred after receiving the Johnson & Johnson vaccines [21].

A recent report by the CDC indicates a likely relationship between the Johnson & Johnson’s Janssen COVID-19 vaccines and blood clots with low platelet condition [22]. These reports of an increased risk of blood clots, particularly of cerebral venous thrombosis, have raised debates on the safety of the COVID-19 vaccines in general. A study by Hansen et al. [23], 2021 also found that the first dose of vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) induces immunogenicity, but sterile immunity is not adequately developed. In Northern Ireland, adverse reaction to the COVID-19 vaccine has been listed as the cause of one death [24]. Similarly, a Norwegian review finds the Pfizer-BioNTech vaccine likely responsible for the deaths of some elderly patients [25]. As of July 27, 2021, experts at the CDC and FDA review every death report following vaccination through the VAERS. These regulatory agencies have not found a causal association, and there is no reason to state that the COVID-19 vaccine causes death. Data from the VAERS and available clinical information (death certificates, autopsies, and medical records) does not establish cause and effect between deaths and reported deaths [15]. Deaths following vaccination equated to deaths caused by vaccines are irresponsible, misleading and scientifically inaccurate [26]. In addition, there is no solid evidence from the World Health Organization and the EMA to table that the COVID-19 vaccines have killed more people than the disease itself which claimed over 3,800,000 lives worldwide [27]. Norwegian health officials have subsequently debunked claims that many aged people died as a result of the vaccine [28]. In a similar understanding of correlation, the MHRA (Medicines and Healthcare Products Regulation Agency) in the United Kingdom noted that side effects of the jabs and some events may have happened anyway, regardless of vaccination [14].

Observational studies and pre-planned statistical analysis done by researchers from the University of Florida showed that global roll-out of the COVID-19 vaccines offers protection against the three so-called variants of concern: 86% for the B.1.1.7 strain first detected in the United Kingdom, 61% for P.1 strain that drove an explosive outbreak in Brazil and 56% for the B.1.351 strain discovered in South Africa [29]. On an average note, vaccination campaigns reduce the direct transmission of SARS-CoV-2 to others by 54% [29]. In another progressive outcome, the Chinese developed vaccine Sinovac offers 83.5% symptomatic protection against the deadly virus, evidenced by interim data from a phase 3 trial in Turkey [30]. Concurrently, the vaccine through large studies on 10.2 million Chileans was found to be 65.9% effective in preventing infections, 87.5% effective in preventing hospitalization, and 86% effective in preventing deaths after two doses [31]. The unprecedented speed with which scientists have developed a safe and effective COVID-19 vaccine has enabled many world economies to reopen [29].

The world has recovered and transitioned out of the worst pandemic in a century [32]. Natural herd immunity would not have been enough to restore the society and globe to normal status without extreme fatalities [32]. All global vaccination programs face some challenges which may impact their success. The suggestion that jabs may be causing deaths among some individuals only undermine inoculation efforts. No vaccine is 100% safe or effective in preventing diseases in all vaccinated people and vaccines aren’t automatically dismissed as a possible cause of death [14]. This paper provides convincing evidence that the COVID-19 vaccines are not directly associated with an increased risk of death following vaccination.

**Evidence in Favor of Casual Association between COVID-19 Vaccinations and Death**

Although the evidence support that COVID-19 vaccines are safe, there are occasional instances where health authorities recognize that each of the authorized vaccines can cause side effects or establish a causal relationship between deaths. A plausible theoretical risk that is not unexpected exist.

**Anaphylaxis following vaccination**

Almost all vaccines are likely to have anaphylactic reactions, but this is rare. Anaphylaxis as an adverse effect occurs at a rate of less than 1 per million doses for most vaccines [32].
Since the emergency authorization of use of Pfizer-BioNTech and Moderna, the CDC detected 21 cases of anaphylactic reaction after administration of reported 1,893,360 first doses of Pfizer-BioNTech (11.1 cases per million doses) of which 71% of these occurred within 15 minutes (December 14–23, 2020 to January 15, 2020) [33]. The Moderna vaccine was estimated to be 2.5 cases per million doses (December 21, 2020 to January 10, 2021) [34]. There are no differences between reactions occurring within 30 minutes of vaccination and those after 30 minutes despite a 15 minutes post-vaccination observation period is recommended for all people [35]. Vaccination is ongoing and updated estimates are been generated to detect additional cases of anaphylactic reactions.

A review of related reports shows that an allergy to the ingredient polyethylene glycol (PEG) causes anaphylaxis to the vaccine and very few people are allergic to PEG [36]. PEG also called macrogols are polyether compounds used widely in medicinal, cosmetic and household products. Some of the vaccines (Pfizer-BioNTech, Moderna, etc.) contain PEG of different novel lipid nanoparticles or compositions (Table 3) [30].

While anaphylaxis is a potentially life-threatening allergic reaction, it can be prevented with timely assessment and management [37]. The CDC recommends the administration of intramuscular epinephrine at all times. Patient screening before vaccination is essential regardless, and those with contraindications should not be vaccinated [37]. COVID-19 vaccination centers should have at least three doses of epinephrine stocked at all times to replace supplies after the drug is administered to patients [37]. However, it is important to note that PEG allergy caused by the COVID-19 vaccine is uncommon and the vaccine still remains safe.

**Possible side effects identified with some COVID-19 vaccines**

There are recent concerns about serious side effects attached to some of the COVID-19 vaccines. These side effects are coincidental and do not provide enough evidence to link a specific vaccine. Moreover, regulatory institutions are constantly investigating these concerns. People have reported certain adverse events associated with the two mRNA vaccines (Pfizer-BioNTech and Moderna). Twenty cases of thrombocytopenia have developed following vaccination with these two vaccines in the United States [46].

Incidence of myocarditis after receiving mRNA vaccines are common [47]. On June 25, 2021, the FDA notified recipients and caregivers about the possibility of heart-related effects and further stated that the chance of having them is low [47]. They often happen in adolescents and young people, and symptoms of shortness of breath, chest pain, and fast-beating are to be observed [47]. The CDC and FDA briefly halted the distribution of the Janssen COVID-19 vaccine due to cases of thrombosis with thrombocytopenia syndrome (TTS). According to the CDC, the vaccine’s known and potential benefits outweigh its known and potential risk in individuals aged 18 years and above and TTS is low. The EMA prompted Janssen to provide warning labels for their vaccines. GBS was reported in some people following the administration of Johnson & Johnson vaccines [48].

Same with AstraZeneca, the EMA and Danish health authorities observed 30 reported cases of blood clots after vaccination of 5 million people [49]. Four European (Denmark, Germany, France, and Norway) countries then paused their distribution before resuming them as a precautionary response [50]. On the contrary and in a different setting, the Covishield locally manufactured version of the Oxford-AstraZeneca has not seen any incidence of blood clots in India. There are also other developed brands of the COVID-19 vac-
### Table 3. Approved vaccines containing polyethylene glycol

| Vaccine and manufacturer | Legal status (as of Jan 2021) | Vaccine type | Excipients | Hypersensitivity data to date |
|--------------------------|-------------------------------|--------------|------------|-------------------------------|
| Sputnik V (Gamaleya Research Institute) | Russia, Palestine | Non-replicating, two-component vector (adenovirus) against spike (S) glycoprotein | Tris (hydroxymethyl) aminomethane, sodium chloride, sucrose, magnesium chloride hexahydrate, sodium EDTA, polysorbate 80, ethanol, water for injection | No events report in phase 1/2 studies (n = 76) |
| Pfizer-BioNTech BNT162b2 | EUA in Argentina, Bahrain, Canada, Chile, Costa Rica, Ecuador, EU, Israel, Jordan, Kuwait, Mexico, Oman, Panama, Saudi Arabia, Singapore, Switzerland, UK, USA, WHO Pending: Australia, India, Japan EUA in Canada, EU, Israel, Switzerland, UK, USA | mRNA-based vaccine (encoding the viral spike (S) glycoprotein) | (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyllbis(2-hexyldecanoate) (ALC-0315), 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), 1,2-Distearoyl-sn-glycero-3-phosphocholine, potassium chloride, sodium chloride, disodium hydrogen phosphate dihydrate, sucrose, water for injection | No anaphylaxis events attributed to vaccine reported in clinical trials (approximately 22,000 participants randomized to active dosing). Approximately incidence of anaphylaxis 1:100,000 with routine use |
| Moderna mRNA-1273 | EUA in Canada, EU, Israel, Switzerland, UK, USA | mRNA-based vaccine (encoding the prefusion stabilized spike (S) glycoprotein) | Lipids (SM-102, 1,2-dimyristoyl-rac-glycero-3-methoxy(polyethylene glycol)-2000 [PEG2000-DMG], cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, sucrose | No acute anaphylaxis reactions reported in clinical trials (approximately 15,000 participants randomized to active dosing) |
| ChAdOx1 (Oxford/AstraZeneca Covishield in India) | EUA in Argentina, Dominican Republic, El Salvador, EU, India, Mexico, Morocco, UK Pending: Australia, Canada | Replication deficient viral vector vaccine (adenovirus from chimpanzees) | L-Histidine, L-Histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80, ethanol, sucrose, sodium chloride, disodium edetate dihydrate, water for injection | No anaphylaxis events reported in clinical trials (approximately 12,000 participants randomized to active dosing) |

From Turner PJ, et al. World Allergy Organ J 2021;14:100517 [30].

EDTA, ethylenediaminetetraacetic acid; EUA, Emergency Use Authorization; EU, European Union; WHO, World Health Organization.
Discussions and Recommendations

Based upon available pieces of evidence, reflections and giving the increasing number of cases of COVID-19 infection globally, vaccination is with no doubt an important task to stop the propagation of the virus.

Currently (as of 31 July 2021), 14.5% of the world population is fully vaccinated with 28.8% individuals who have received at least one dose of a COVID-19 vaccine representing 4.11 billion doses administered and 37.58 million doses daily [51]. While these figures are promising and inch closer to beating the pandemic.

Recent evidence shows that some people are unwilling to get vaccinated [52]. Reaching the world's most vulnerable population, convincing them about the vaccine and making them trust vaccine developers remain a challenge [53]. A related study done shows that 27% of Americans would not get the COVID-19 vaccines even if it is free and deemed safe by scientists [54]. A salient and widespread concern expressed by the general public also a key driver of vaccine hesitancy is the speed at which the COVID-19 vaccines were developed [55]. In recent times, hesitancy to the COVID-19 vaccine is due to safety concerns and side effects whereas mistrust of the vaccine and government also influence fears of the vaccine [56].

While these feelings are normal and understandable, public trust in the COVID-19 vaccine and vaccination is essential, as is the effectiveness of the vaccine itself [57]. The general population will gain confidence in the COVID-19 vaccines as information surrounding them becomes available, especially when those that didn't result in success are not shut down or covered [55]. The effectiveness, safety, and pace at which the vaccines were developed must be demonstrated [55]. This will make people believe that vaccine developers were only pursuing successful and effective avenues [55]. For instance, the speed at which the vaccines were developed does not mean regulatory corners were cut. Developments were facilitated by extensive research with high levels of international collaboration among researchers and massive financial support [58]. The grave impact of the pandemic invested more resources into developing a vaccine to lessen the consequences as soon as possible [59]. The world was able to funnel more experts and financial resources into vaccine development [59]. These factors did not compromise the safety of the vaccines.

Consequently, analysis of adverse events associated with the COVID-19 vaccines provides an opportunity to examine and evaluate the safety outcomes of vaccination programs in a different setting. Vaccination programs and efforts invested need to be closely monitored deaths following vaccinations. There must be accountability, evaluation, and ongoing research to achieve the goal of controlling the pandemic and the prevention of related deaths. This can also increase the breadth of protection conferred by the COVID-19 vaccines. Openness to public scrutiny and public institution engagement with the general population is important [57]. Most of the unvaccinated are still open to these ideas and presenting transparency redouble efforts to reach the unvaccinated [60].

Addressing and demonstrating these safety, immunogenicity and efficacy concerns of the vaccine in a broad range of settings will be necessary to restore trust in a way that supports effective vaccine delivery and acceptance.

Furthermore, vaccine-hesitant groups are peddling misinformation about the COVID-19 vaccination deaths and making up conspiracy theories aimed at eroding trust in the vaccines. This misinformation threatens people's confidence in taking the vaccine [58]. They capitalize on the deaths of people especially those who died of old age or underlying health conditions after receiving the shot to undermine vaccination roll-out and sometimes they manufacture stories that never happened [53].

This misinformation, although false is now taking shape [53]. Anti-vaccination activists take a quote or a bit of them, isolating part and removing all other context making them meaningful in society [53]. When fake stories of deaths are tied to the vaccine, there is an emotional grab [53]. The general public should not be alarmed unnecessarily. They must look deep to scientific evidence instead of breeding uncertainties [53]. There is always a probability that fatal outcomes will happen to a small percentage of people after vaccination even if the vaccines are perfectly safe [53]. Uncertainty leads to doubts and worries, making people prone to misinformation [53].

Although experts are still learning a lot concerning the COVID-19 vaccines, there are clear benefits to getting vaccinated. Vaccination is key to understanding the benefits of the vaccine which outweigh the side effects [61]. The public health benefits of the vaccine are the reasons for its use [61].
The mass population have to be educated and awareness campaigns have to intensify than before concerning the relevance of accepting the vaccine. We would return to a pre-pandemic normal state, have a functioning society and the vaccine will keep people safer and healthier than if not vaccinated. Everyone’s activities and access to education, health job and family protection will be impaired if the public does not take collective measures [58]. We can also start meeting safely again without a facemask, family hugs for the first time in over a year can happen [62]. In short, the vaccine is a game-changer in many areas. The understanding of these factors by the majority can enlighten the general population to get vaccinated and be equipped with the information needed to reassure others. As recognition grows for the importance of the vaccine, more people may consider it, creating a sense of urgency. In addition to the above recommendations, it is in the best interest of individuals who wish to get the shot to have specific questions about whether it is safe for them. Consulting qualified healthcare providers, trusting experts, and reputable sources are critical now to filter out misinformation about vaccine-related fatalities [63]. For individuals with allergies, it is necessary to get confirmation from their healthcare providers. Taking the shot is not coercion and people must ask questions, seek answers to make informed decisions, and get specific concerns addressed. Independently, people can make their research and corroborate with others to ensure the information they are receiving is credible [53].

Seeing the vaccine as dangerous when there is no scientific data to support that hypothesis is a misinterpretation [64]. It would be naïve for the general public to assume that the newly developed vaccine will be uniformly less problematic than without doing any research or investigate work [64]. In terms of vaccine side effects, we should anticipate both success and possible failure perhaps [12]. Vaccine safety monitoring is ongoing, and according to the CDC, the COVID-19 vaccine has a “reassuring safety profile”. Therefore, evidence to date supports COVID-19 vaccination and provide lessons to implement future vaccination programs.

**Conclusion**

The COVID-19 vaccines are rigorously tested and monitored and deemed safe for controlling the pandemic. Serious adverse effects and deaths related to the vaccine are uncommon and very rare.

The public, scientists, developers, and health providers have a role to play in ensuring successful vaccination campaigns. This includes the public disregarding misinformation about vaccine-related deaths, proper screening for contraindications by health professionals, and reporting side effects accordingly through the VAERS or defined channels. Credible institutions like CDC, FDA, EMA, the Africa CDC, and other regulatory authorities in various countries also have the responsibility to review deaths reports and serious cases of adverse events such as life-threatening illness, hospitalizations, and permanent disabilities. This must be done for all individuals and brands of the COVID-19 vaccine. Should a potentially new safety concern or events be detected by these regulatory bodies, the signal must be thoroughly assessed, and the needed public action is taken where necessary. Drawing a hasty conclusion that the vaccines are linked to the recent claim of death based on spontaneous happening is not scientifically valid. Evidence about the safety and effectiveness of the COVID-19 vaccines is highly favorable.

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