

# Where Did We Go Wrong with This Pandemic?

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**How to cite this paper:** Gernon, L.W. (2022) Where Did We Go Wrong with This Pandemic?. *Open Journal of Emergency Medicine*, 10, 67-79.  
<https://doi.org/10.4236/ojem.2022.102006>

**Received:** February 9, 2022

**Accepted:** April 11, 2022

**Published:** April 14, 2022

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## Abstract

Two years into the SARS-CoV-2 pandemic the shining light of hope has been the speed at which vaccines have been developed based on a new platform technology allowing breakthroughs with other novel, neglected and emerging infectious diseases. Lurking in the shadows has been the various health care systems related to surveillance, data collection, access to basic health, fear, nationalism, government distrust, vaccine skepticism, global supply chain shortages, health worker shortages and misinformation. In this paper, I have tried to highlight the areas where lessons learned can make a difference for our response to the next pandemic at the local, state, national, regional, and global level.

## Keywords

Surveillance, SARS-CoV-2 Pandemic, Immunology, Vaccinations, Pandemic Response, Death Certificates, Vaccine Nationalism, WHO

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## 1. Introduction

### Ignoring History

Without having to reach far in the past, one can predict over the past 20 years the warning signs of emerging novel infectious diseases and the reemergence of drug resistant pathogens. Outbreaks of, cholera in populations displaced by war and famine, West Nile Virus, Zika, Dengue, Ebola in West Africa, Systemic Acute Respiratory Syndrome (SARS), Middle Eastern Respiratory Syndrome (MERS), HIV, novel influenza strains (H3N2, H1N5) and now SARS-CoV-2. It was not a matter of if, we would face a global pandemic, but when. There has been a hodgepodge of pandemic preparedness at the international, regional, federal, state and municipal levels, more in line with checking the box than in true planning and response. Sadly, politicians control monetary resources and have not seen the relevance and importance of funding

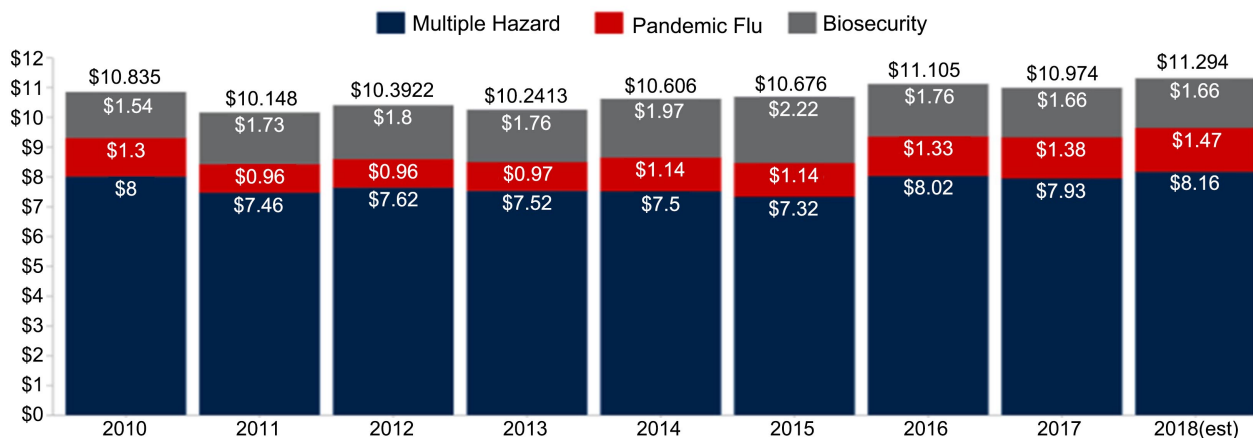
public health disease surveillance as they have with the military industrial complex for the Department of Defense. Short of a nuclear apocalypse, the wrath of mother nature supersedes any manufactured biological weapon of mass destruction (Figure 1).

Only 12% of the health security budget went to pandemic preparedness, although the Department of Defense spent sixty-two times more than the allocation to Health Security [1], despite more American deaths from this pandemic compared to those lost in wars. Had our elected officials and politicians approached pandemic preparedness like bioterrorism and preparation for war, our mindset would have been initiative taking and proactive, contrary to a reactive defensive posture. Sustainable, consistent funding at local, state, federal and international levels, for disease surveillance and training epidemiology intelligence officers must be a priority for global health threats. Drills, training, tabletop exercises conducted on a regular basis involving private-public sector partnerships at all levels reinforce the All-Hazards approach and One-Health model for the next pandemic.

**Pandemics are global and require a coordinated global response.**

Pathogenic bacteria, virus, fungi are unaware of borders and national boundaries. Though draconian measures such as lockdowns, quarantine, self-isolation, banning of flights with citizens from areas of new mutations/variants do not stop the disease, but may slow transmission (theoretical) with the result of not burdening health care system resources, I question if they are effective measures. The concept of “flattening the curve” (Figure 2) is about preventing a surge that may inundate the health care system and does not imply less people will become infected. Note the area under the curve is the same. This has been a disease difficult to control when up to 40% of those infected have mild symptoms or are asymptomatic [2].

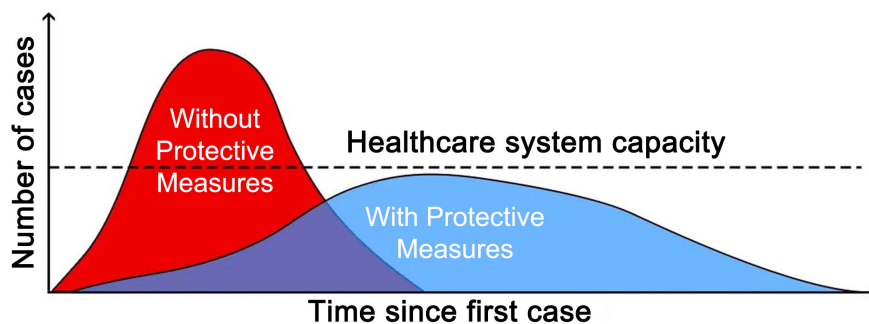
U.S. Government Spending on Pandemic Preparedness, Health Security (In billions)



Watson C, Watson M, Gastfriend D, Sell TK. Federal Funding for Health Security in FY2019. Health Secur. 2018 Sep/Oct;16(5):281-303. doi: 10.1089/hs.2018.0077. PMID: 30339096.

A breakdown of federal government spending aimed at preparing for health crises. (Data: "Federal Funding for Health Security in FY2019," Health Security)

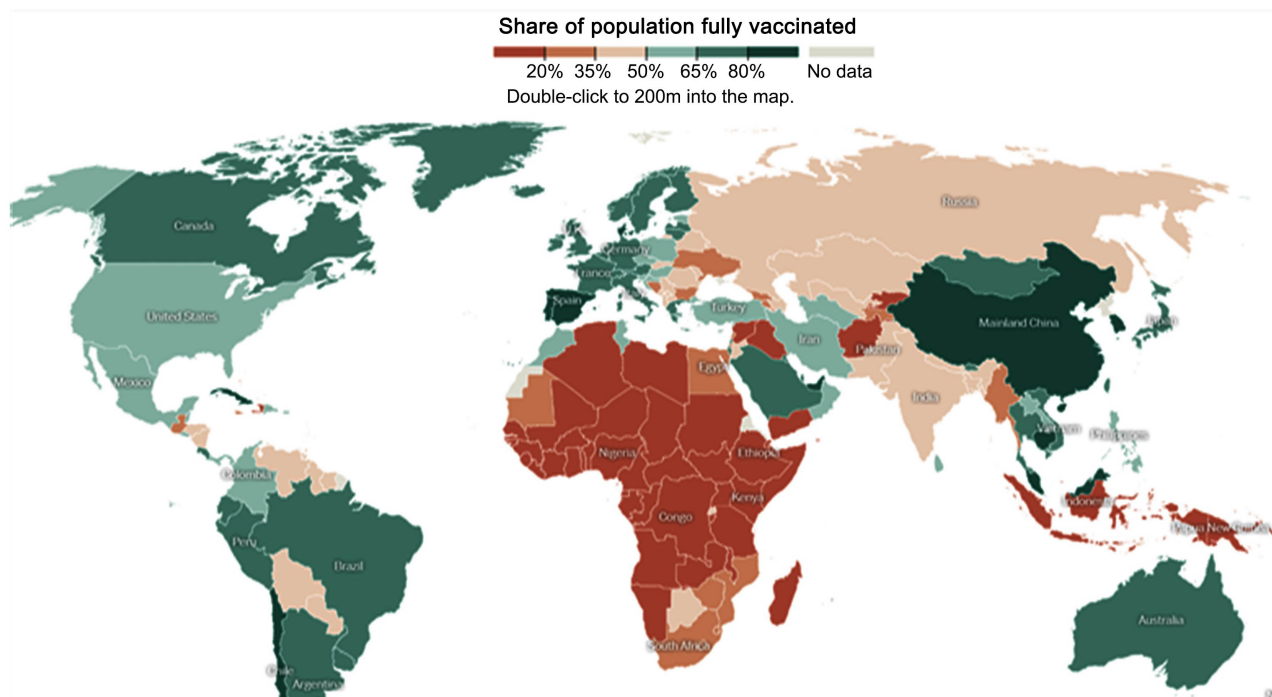
Figure 1. Federal funding for health security 2019.



Adapted from CDC /The Economist

**Figure 2.** Flattening the curve.

The World Health Organization (WHO) as the leading global public health agency is limited by its role as a technical support agency to those member states who request assistance. Constraints to involvement in a public health crisis as we have seen with the COVID-19 pandemic are determined by World Health Authority, where high funding nations can manipulate policy decisions for their own national interest, and outbreak information for surveillance and data collection in a timely manner is dependent on truth and good will of member states without the impunity of travel bans and economic isolation. As well-meaning as the COVID-19 Vaccines Global Access (COVAX) partnership is, the failure of WHO to secure and ensure COVID vaccines to lower income countries during a global pandemic will have tarnished its reputation despite the numerous successful accomplishments related to humanitarian crises, childhood vaccinations, and smallpox eradication (**Figure 3**). To restore the WHO to a relevant agency



**Figure 3.** Share of global population fully vaccinated (Source New York Times Jan. 2022).

the following issues need to be addressed: give voice to multiple stakeholders, improve transparency, performance and accountability, exercise closer oversight of regional offices, exert legal authority as a rule-making body, and ensure predictable and sustainable financing [3].

#### **Failure to understand basic immunology and virology**

For many infectious diseases, naturally acquired immunity is known to be more powerful than vaccine-induced immunity as it often lasts a lifetime. With the COVID-19 pandemic there have been mixed messages from the “Medical Experts” on transmission, natural immunity, herd immunity, vaccine induced immunity, booster policies, effective treatments, etc. Back to the basics, which have stood the test of time. Our understanding of the immune system is still nascent despite the advances in knowledge acquired from the HIV pandemic. All species have evolved an immune system to combat antigens (pathogens) which may be harmful to its survival. With a daily bombardment of hundreds of antigens, a robust immune system is key to survival. In simplistic terms, humans have developed an immune system that has traditionally been categorized into three systems; 1) Natural Barriers (skin, mucous membranes, ciliated epithelial cells) very much like a fortress with a moat which acts to prevent or contain invaders (antigens) from establishing a presence and remaining a threat. 2) Innate (Nonspecific) immunity, the immediate first responders (antigen presenting cells, dendritic cells, complement) with the main function of killing, containment and capturing these invaders. 3) Cell Mediated (Specific) immunity takes longer to respond but is designed to activate T cells to destroy the antigen, B cells to produce specific antibodies (Ab), IgM and IgG to target and block the antigen from accessing cellular receptor sites, and memory cells which catalog the antigen allowing for an expedient and robust response upon re-exposure [4]. IgG neutralizing antibody levels (Nab) have been shown to fall over the course of several months, between 60 and 90 days from the initial infection [5]. Several reports have implied immunity lasts until 7 - 12 months [6]; however, protection is not just about antibody titers. Measuring only circulating antibodies can be misleading as it excludes the detection of the memory cell pool, which can exist in the absence of detectable serum Ab levels and is a pre-requisite to maintain protective immunity in the long term [7]. The virus-specific memory cells increase over time after natural infection [8]. We currently lack cost effective commercial testing for measuring memory cells, however a study of survivors from the 1918 influenza pandemic reveals that antibodies to the strain have lasted a lifetime [9]. Several randomized controlled trials of protection from natural immunity vs. vaccination have shown superiority of natural immunity over vaccination with statistical confidence [10]. The phenomenon of reinfection in the COVID-19 recovered is low. The protective effect of an earlier infection is on par with the primary available COVID-19 vaccinations, a systematic review of the literature in May 2021 found that SARS-CoV-2 reinfection was an uncommon event, ranging from 0% - 1.1%, with no study reporting an increase in infection risk over time [11]. However,

the level of protection against re-infection as assessed by PCR positivity in one study was estimated to be 50% in people aged over 65 years old [12] which led to the recommendation of a third vaccination for the two series primary vaccination for select populations (elderly and immunosuppressed individuals from chronic diseases or immunosuppressive medications) who may not have mounted a sufficient protective response after the primary series [13].

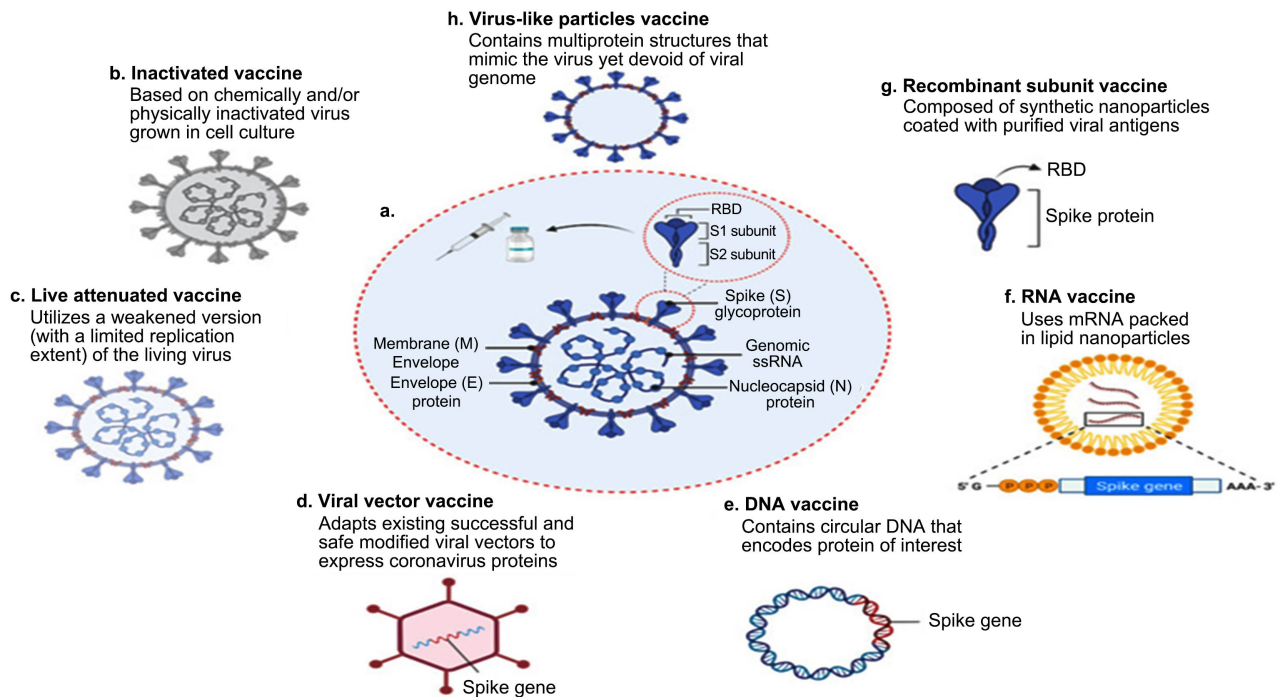
The replicative process of viruses, including SARS-CoV-2 shares the ability to enter a cell through a specific receptor site and “high jack” by reinserting its genome into the normal replicative assembly process to create more virions which are released to propagate the infection. SARS-CoV-2 consists of twenty-nine proteins. While waiting for the development of a vaccine, measures such as handwashing, social distancing, masking and self-isolation were the best tools available hoping to slow transmission and not overwhelm the health care system. SARS-CoV-2, like other RNA viruses, is prone to genetic evolution while adapting to their new human hosts with the development of mutations over time, resulting in the emergence of multiple variants that have distinctive characteristics, associated with enhanced transmissibility or virulence, reduction in neutralization by antibodies obtained through natural infection or vaccination, the ability to evade detection, or a decrease in therapeutics or vaccination effectiveness. Not a new or surprising phenomenon.

Vaccination, the introduction of a safe antigen to prime the immune defenses without causing the disease is the way forward out of this pandemic and is the cornerstone of public health prevention for reducing deaths and transmission. Manufacturers were able to produce an effective COVID-19 vaccine in a quarter of the time it took them to develop mumps vaccine is a remarkable feat (Figure 4).

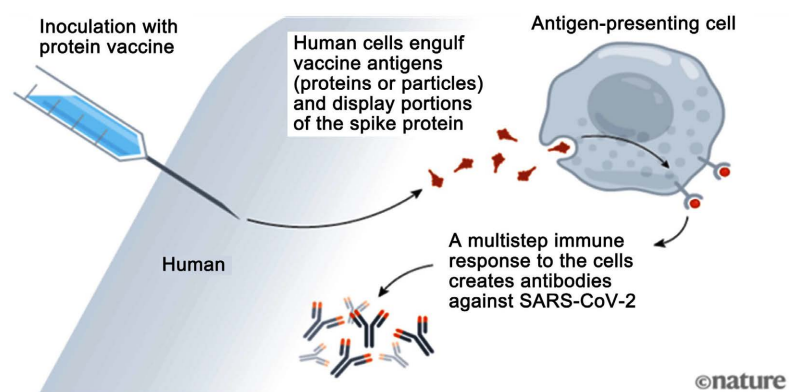
Early in the pandemic, the current vaccines (single protein) targeting the Spike protein reduced the mortality from SARS-CoV-2 infections, however as the virus has started to mutate at the Spike protein region, we need to consider multiprotein vaccines (Figure 5).

The longer SARS-CoV-2 virus circulates, the greater the opportunities to mutate through natural evolution. The emergence of virus variants can pose new challenges. Opportunities were missed when vaccinations early on did not include the total population. A phased approach to vaccinate those first felt to be at highest risk for serious disease (elderly, those with co-morbid medical conditions and the immunosuppressed) made sense, but not including all school aged children (even those in day care) will prove to be a mistake as communicable diseases do propagate in childcare settings [14]. In pediatric SARS-CoV-2 cases, fecal virus shedding long after nasopharyngeal negative swabs has been seen [15].

How much cellular versus humoral immunity contributes to protection after natural infection and vaccination is not fully understood. Studies point at NAb as a key element of immunoprotection, with cellular immunity likely to provide



**Figure 4.** COVID-19 vaccine platforms (Source: *Basel* 2021 Oct 18; 9(10): 1196. doi: 10.3390/vaccines9101196).



**Figure 5.** Multiprotein vaccines (Source: *Nature* 599, 359-360 (2021) doi: <https://doi.org/10.1038/d41586-021-03025-0>).

additional longer-term protection especially against severe disease and death [16] [17]. We must look beyond NAB as our only correlate of protection, since it alone may not be sufficient and durable, and low titers coupled with cellular immunity may induce more durable protection against reinfection [18]. There are no data currently on the long-term effectiveness of booster doses to the general population, so it remains unknown at this time how long benefit might last. The effect of booster doses on transmission is unknown. Therefore, the WHO stance on booster doses being unnecessary to the general population, particularly when 61% of the global population has received only one vaccine in a two series vaccine with less than 10% of populations in low-income countries receiving one vaccine [19]. Protection from one vaccine is better than no vaccine but is considered an incomplete COVID vaccine series.

Countries that are traveling down the road of multiple booster vaccinations to the general population run the risk of noncompliance and loss of public confidence in the vaccine, public health and the scientific community, adding credence to the antivaxx mentality. The bottom line is that current vaccinations reduce mortality...PREVENT DEATHS. Any suggestion that it lowers community transmission and ensures herd immunity is premature, speculative and highly unlikely.

**Data collection and analysis: inaccurate data leads to poor public health decisions**

## 2. Mortality Data

How are COVID-19 deaths counted? It's complicated, confusion continues over whether people die "of" COVID-19 or "with" COVID-19. The essential question is what are your risks of dying from SARS-CoV-2 infection?

Not a straightforward answer as death rates during the first wave varied high as 16 per cent for people over 90 but is 0 per cent for children under 4 in high income countries. Estimating the real death rate is hard for two reasons. First, the odds of dying from COVID-19 vary depending on a person's age, sex, co-morbid medical conditions and the standard of care received. This means death rates will vary from place to place and at various times.

An accurate estimation of the infection fatality risk of SARS-CoV-2 is difficult. Even if all symptomatic infections were diagnosed, which has not happened so far in most countries, asymptomatic infections cannot be clinically identified. Therefore, estimating the infection fatality risk relies on population based seroepidemiological surveys that provide an estimate of the proportion of individuals infected, regardless of symptoms [20]. Because determining the number of deaths from COVID-19 is often difficult, calculation of the infection fatality risk is complemented with data on excess overall mortality as seen in the chart. The assumption is that the peaks and blimps are due to COVID-19 deaths (Figure 6).

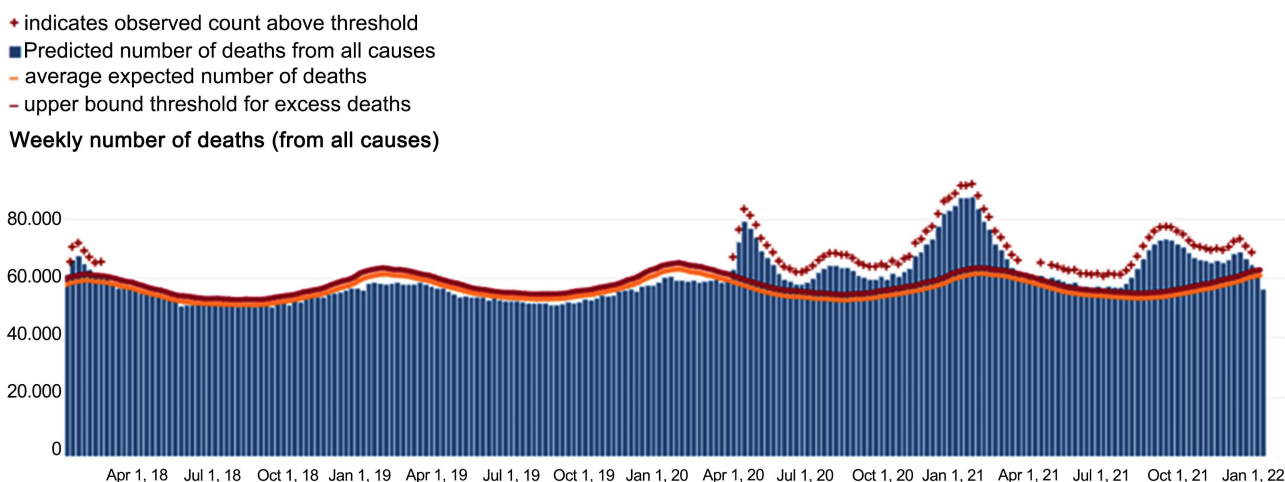


Figure 6. US deaths (Source: [https://www.cdc.gov/nchs/nvss/vsrr/COVID19/excess\\_deaths.htm](https://www.cdc.gov/nchs/nvss/vsrr/COVID19/excess_deaths.htm)).

The best way to work out how many people have been infected early in the pandemic before the introduction of vaccinations was to test the blood of thousands of people to see how many have antibodies to SARS-CoV-2, and then extrapolate the results to entire countries. But antibody surveys can produce a misleading picture because of false positive and false negative results [21].

### 3. Death Certification

Other data sources for tabulating deaths are from Death Certificates. Appropriate cause of death reporting is vital in the pandemic circumstance for effective planning of control measures. Death certificates, are the most reliable source of data and contain information not available anywhere else, including comorbid conditions, race and ethnicity, and place of death. COVID-19 deaths are identified using a new ICD-10 code. When COVID-19 is reported as a cause of death—or when it is listed as a “probable” or “presumed” cause—the death is coded as U07.1. This can include cases with or without laboratory confirmation. In the U.S., 20% - 30% of death certificates were wrong before the pandemic.

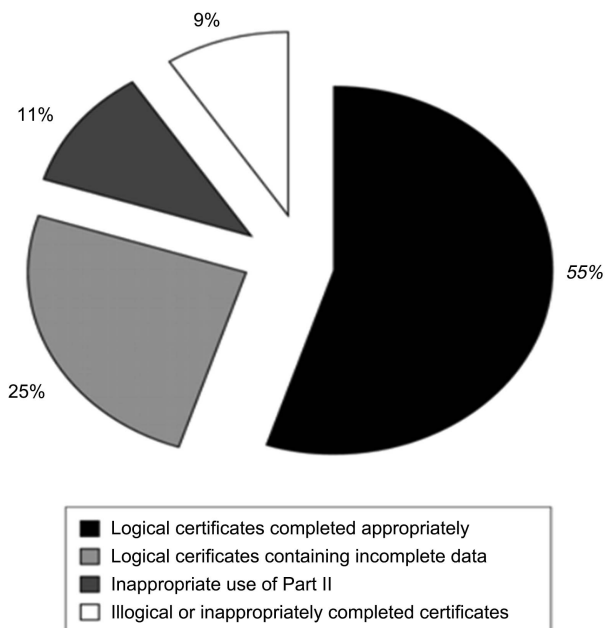
The autopsy remains an important method for ensuring the quality of mortality statistics [22] and are considered the gold standard but are rarely performed since the Joint Commission on the Accreditation of Hospitals (JCAHO) eliminated the requirement for a 20% autopsy rate with estimated rates currently  $\approx$ 8% overall, including forensic cases, but only 4% among in-hospital deaths. As a result, health statistics can be skewed [23].

Do we always know cause of death? As Physicians we make our best, educated guess based on our personal knowledge of the patient’s history or information obtained from a medical chart review. How accurate are death certificates? Research on this topic indicates that the error rate in death certificates ranges from 10% to 55%. A review of 1000 death certificates showed 55% of certificates were completed to a minimally accepted standard, and many of these failed to provide relevant information to allow adequate ICD-10 coding. Nearly 10% were completed to a poor standard, being illogical or inappropriately completed [24].

Despite this being a recognized flaw in the reporting system, concerted effort on how to correctly fill out a death certificate needs to be addressed with training at the medical school, residency training and continued education levels (Figure 7).

### 4. Vaccine Adverse Event Reporting System (VAERS)

This is a surveillance program managed by the Center for Disease Control (CDC) and Food and Drug Administration (FDA) to monitor vaccine safety and adverse events, a federal vaccine injury compensation program, to eliminate the potential financial liability of vaccine manufacturers due to vaccine injury claims. It is based on submissions by the public and is prone to unverified reports, misattribution and inconsistent data quality [25]. As per a Congressional mandate, CDC continues to publish the VAERS data. For 2022 per VAERS data,



**Figure 7.** Appropriate completion of death certificates. (Source: Swift, K West Death certification: an audit of practice entering the 21st century J Clin Pathol 2002; 55: 275-279).

the greatest number of reported deaths by Vaccine type from 1990 to the present has been due to COVID-19 vaccination (18,078 deaths) with the risk of dying from COVID vaccine being 171.8 times greater than flu vaccine [26]. It is no wonder the antivaccine community has taken this information to question the safety of COVID-19 vaccinations.

**Pandemics do not create a weak health care system; they only exacerbate the flaws in the system**

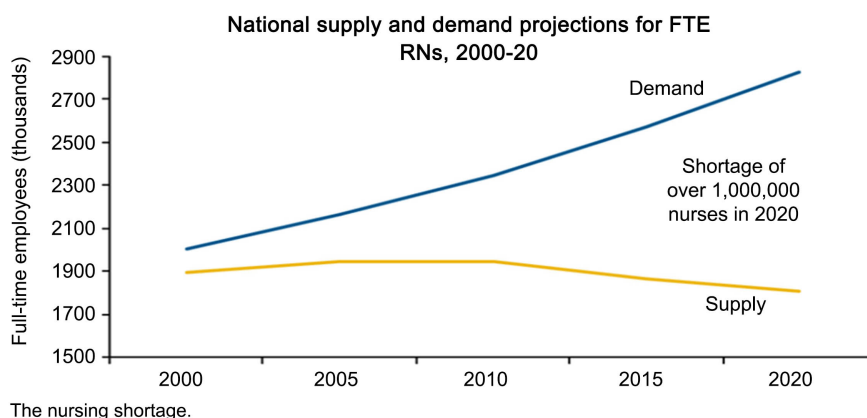
The COVID-19 pandemic has disrupted the Global and U.S. health care systems. Despite COVID-19 vaccinations the number of patients presenting to Emergency Departments testing positive for SARS-CoV-2 by PCR has been increasing. There are multiple reasons why; first, anyone being admitted to a hospital for whatever reason must have a PCR COVID test and second, the screening criteria for COVID testing in emergency departments are like casting a wide net, everyone gets tested. What the Press does not report is that patients who are not vaccinated are more likely to present and die from SARS-CoV-2 pneumonia and hypoxia. We do see patients presenting to the Emergency Department who have been vaccinated testing SARS-CoV-2 positive with mild symptoms, not requiring hospitalization. Sadly, emergency departments, hospital general medical beds, and critical care beds are busier not because we are being inundated with ill COVID patients, but because Primary Care Providers no longer care for patients, having closed their offices and using telemedicine as an alternative. There are limitations with telemedicine which include the basics of a physical exam. On numerous occasions, patients have been referred to the Emergency

Department reflexively for an evaluation or testing due to the limitations of, telemedicine visits or lack of access to primary care offices. Besides the primary care network closing its door, we also see specialists (Surgeons, Orthopedics, Cardiology) deferring visits and procedures unless it is deemed an emergency. As a result of this and the inability of patients to receive outpatient services, they delay treatment until a crisis develops. Little wonder that more patients are dying at home and deferring care. Staff in emergency departments, hospitals (general medical and critical care) have taken the brunt of work during this pandemic. Emergency Departments have become the default primary care office, vaccination center, infusion center, employee health care center besides the main function of an emergency center. There was a shortage of nurses prior to this epidemic, but with the added responsibility and mediocre compensation and appreciation, this pandemic has exacerbated that shortage [27] (Figure 8).

In the 1980's I witnessed health care providers shunning HIV patients behind the fear of contagion. The beast has reared its ugly head again with this pandemic. The challenge for US Primary Care Providers will be to embrace and insert themselves back into the health care system as the prevention specialists and gatekeepers for health care. In comparison to other well-resourced countries, Australia and New Zealand were the best prepared. Both had universal health coverage and up-to-date pandemic plans. In Australia, guidelines were in place for PCP's for both pandemic influenza and public health emergencies. Widespread testing was rapidly established, and national and state governments assisted in the provision of personal protective equipment (PPE) to general practice. New Zealand also had an updated pandemic plan, and District Health Boards led the pandemic response with good coordination of primary care and public health. Government support was provided to primary care for their increased workload, although many practices still had a shortfall [28].

The US does not have universal health coverage. Although the US pandemic plan had been updated in 2017, primary care had no defined role [29]. The National Security Council Directorate for Global Health Security and Biodefense, set up to manage US response to disease outbreaks and pandemics, was disbanded in 2018. Primary care was left on its own to assist in the response, and to deal with changing, confusing, and at times conflicting recommendations from local, state, medical specialty, and federal authorities [30]. Primary care physicians had to find their own PPE for office visits, and most were dependent on fee-for-service funding. Prior to the pandemic, telehealth was uncommon, so the rapid pivot to virtual visits happened without consistent changes in payment support and required a leap of faith by physicians that they would remain solvent. The US has had a quarter of the world's cases of COVID-19, thought to be due to delays in testing, inconsistent messaging, variability in social distancing guidelines, health disparities accentuated by decreased access to health care, and variable support for public health guidelines by governments and the public [31].

Lockdown drastically reduced access, to some degree mitigated by telehealth. Comprehensiveness and continuity of services have suffered, as addressing the



The nursing shortage.

**Figure 8.** The nursing shortage US (Source: Linda V. Green, Using Operations Research to Reduce Delays for Healthcare September 2008 DOI: 10.1287/educ.1080.0049).

pandemic was prioritized over dealing with non-COVID-19 conditions. Countries that have fared the best are the ones with universal health coverage, updated pandemic plans that include primary care, and good government and public support for the public health measures. In order for the US to learn from the lessons of this pandemic there will need to be; increased funding for preparedness, surveillance and data collection/analysis; Congressional implementation of laws related to pandemic emergencies given the Founding Fathers left health care issues under the purview of states' rights (Police Powers), and a hard and serious look at Universal Health Care which would resolve the current fragmented approach we face in this country, a daunting task with many compelling interests in the financial milieu.

### Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

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