AN END IN SIGHT A Plan to Reduce COVID-19 Deaths to Near Zero

COVID Collaborative

DECEMBER 2022

Author

Steven C. Phillips, M.D., MPH Vice President of Science and Strategy COVID Collaborative

Dr. Phillips is a medical epidemiologist who is certified by the American Board of Internal Medicine and the American Board of Preventive Medicine. He is a Fellow of the American College of Epidemiology and the American College of Occupational and Environmental Medicine.

About COVID Collaborative

The COVID Collaborative is a national bipartisan assembly of experts, leaders and institutions in health, education and the economy, and associations representing the diversity of the country, united to turn the tide on the pandemic by supporting global, federal, state, and local COVID-19 response efforts. COVID Collaborative includes former FDA commissioners, CDC directors, and U.S. surgeon generals; former U.S. secretaries of Education, Defense, Homeland Security, and Health and Human Services; leading public health experts and institutions that span the country; leading business groups and CEOs; groups representing historically excluded populations; major global philanthropies; and associations representing those on the frontlines of public health and education.

Disclaimer

The contents of this white paper represent the views and opinions of Dr. Phillips and does not necessarily represent the views or opinions of the COVID Collaborative or of its constituent member organizations. The logo of the COVID Collaborative on this paper does not constitute an endorsement of the content by its member organizations.

Executive Summary

After nearly 100 million cases and 1.1 million deaths from COVID-19, Americans are witnessing the move from a highly disruptive and protracted pandemic to a new endemic phase of "living with the virus." Americans want to live in a dynamic society that protects public health while returning to prosperity and individual freedoms. To achieve these twin goals, the nation needs a plan that focuses on where deaths and hospitalizations are concentrated, and also on where restrictions and mandates can be eliminated. We have proposed an evidence-based schema that identifies all Americans in a binary risk-based Vulnerable/Non-Vulnerable framework. This demarcation allows a clear focus on the high-risk brunt of the human toll, while unburdening those at low-risk from avoiding virus exposure as they return to normal activity.

Our 6-point National Plan, based on a comprehensive National Framework, contemplates near-zero deaths and less than 1,200¹ average weekly hospitalizations from COVID-19. With the targeted deployment of two major life-saving interventions – up-to-date vaccination and Paxlovid coverage – focused on the "*Vulnerable Population*," (defined here as everyone age 65 and above, and including those under 65 who live in Long Term Care facilities), we believe deaths from COVID-19 could be decreased by about 74 percent² and weekly hospitalizations by about 53 percent¹ across the entire population. Similarly, as avoiding exposure is no longer the goal in the "*Non-Vulnerable*" (under age 65) population, pharmaceutical and non-pharmaceutical interventions can be selectively relaxed or eliminated in this group.

Within this binary "Vulnerable/Non-Vulnerable" population framework, it is critical to recognize the principle that where the public health interests of these two groups intersect, it is the protection of the high-risk Vulnerable that prevail for setting policy and best practice. This means that special consideration should be directed at those real-world scenarios where these areas of intersection occur with regularity, and where the Non-Vulnerable population has a responsibility to take protective measures seriously.

Invoking this approach, the country can capture simultaneous public health benefits *and* positive societal impacts. In-person education, commerce, employment, travel, recreation, and entertainment can return to normal, while at the same time serious disease can be rapidly reduced and eventually approach near zero. Public health benefits need no longer be balanced directly against social, educational, and economic costs. Such an effort will require significant changes in public policy and clear messaging,

including eliminating most restrictions among the Non-Vulnerable population and institutions.

Background

Nearly three years into the COVID-19 pandemic with 100 million cases and 1.1 million deaths, the country has migrated from an acute pandemic-phase to a "living with the virus" endemic-phase. Although there is not a bright-line distinction between pandemic and endemic phases, most <u>experts</u> agree that the current relatively mild, stable, and manageable state of SARS-CoV-2 approaches endemicity.

Individuals, communities, and institutions are attempting to balance the trade-offs between health-protection and returning to normalcy. <u>National prosperity</u>, commerce, educational attainment, social development, and mental health have all <u>suffered greatly</u> due to the pandemic and its safeguards, and a sense of exhaustion from restrictions is sweeping society. The country, however, is still on a course of incrementally adjusting pandemic-phase policies, rather than making a strategic pivot to formulate a decisive and sustained endemic-phase response that both manages public health risks and respects individual choice. The nation needs greater clarity on where things stand with COVID-19 and where we are headed.

National Goals

The assessment and policy recommendations presented here are in support of new endemic-phase national goals--near-zero deaths and less than 1,200¹ weekly hospitalizations. We demonstrate that this is realistic and achievable by year-end 2023 with currently available tools. It is a significant departure from the March 2022 pandemic-phase <u>National COVID-19 Preparedness Plan</u>, where the key goal was to "protect against and treat COVID-19."

Three endemic-phase factors – a lower mortality and serious disease risk from <u>"later</u> <u>Omicron,"</u> (defined by the CDC to be between April and October 2022), high levels of vaccination and natural immunity among the population as a whole, and a predominant concentration of deaths and hospitalizations in the elderly –- support this re-set of COVID-19 policy without returning to the grim societal trade-offs between health and prosperity.

First, while the "later Omicron phase" features the <u>fastest spreading</u> virus in human history, it is also <u>much less virulent</u> than its predecessors and is highly susceptible to current vaccines and oral treatments in preventing serious disease. Figure 1 shows that later Omicron is less than one-third the mortality risk of Delta or Early Omicron for all populations, especially for the elderly and those with underlying medical conditions.

The <u>second</u> factor enabling a reset is the high and reasonably durable and dynamic protective level of population immunity—due to ongoing unavoidable natural infection and re-infection, further enhanced by additional immunity from vaccinations. While the level of population immunity is unlikely to reach levels needed for <u>herd immunity</u> and elimination of the virus, it is likely that its ongoing transmission will continue to provide a significant buffer against serious disease, especially in the Vulnerable Population.

Finally, given the lower mortality risk to the population as a whole, and increased immunity, it is no surprise that *serious disease* (defined as hospitalizations and deaths due to COVID-19) is concentrated more than ever among the *elderly* (defined as age 65 and older).

This stark observation calls for in-depth analysis to understand and mitigate the drivers of a highly <u>concentrated</u> toll in the Vulnerable Population. These are the people who must not be left behind as the nation moves from the acute pandemic to an indefinite endemic-phase.

Our proposed National Framework is built on knowledge of the virus behavior, the human host biological response, as well as the external environment and interplay of complex social, cultural, economic, and political factors.





Crude Mortality Risk per 100 Patients Hospitalized Primarily for COVID-19 for Multiple Patient Groups, by Predominant Variant Period, United States, July 2021–June 2022

Source: Jetelina, "Who Is Dying from COVID-19?" 18 Nov. 2022



A National Framework: 10 Policy Pillars to Manage COVID-19

PILLAR ONE

Focus on preventing only serious disease

Preventing exposure, infection, and transmission in the general population is practically unachievable with currently circulating Omicron sub-strains. Nearly <u>every American</u> has been and will continue to be infected regardless of vaccination status or preventive behavior. Based on CDC data, it is estimated that in the past <u>eleven months</u>, there were 116 million first infections and 209 million reinfections in the U.S. population.

Largely because of these intense cycles of infection, these <u>authors</u> calculated that "between December 1, 2021 and November 9, 2022, protection against an omicron infection leading to severe disease increased from 61% to 98% nationally."

Exposure-avoidance can incrementally decrease the likelihood of infection, but it cannot come close to eliminating it. The diminished risk of serious disease in the *Non-Vulnerable* (under age 65) population is being increasingly recognized. In the week ending November 30, this group of about 276 million Americans was responsible for 8% of national COVID-19 deaths. This makes the relative risk of dying from COVID-19 57 times greater for those 65+ versus those under age 65.³

In this setting, exposure-avoidance for Non-Vulnerable Americans is not a successful strategy for mitigation of serious disease and will result in significantly negative societal impacts for modest incremental health benefit. The CDC still <u>recommends</u> masking for ten days and testing on day five in *all* incidents of known exposure, even when no symptoms develop. The U.S is currently averaging nearly 500,000 weekly reported cases of positive tests per week. An estimated 5% of all cases are reported, so actual infections are likely in the range of 10 million per week. There are no reliable studies on the number

of CDC-defined "exposures" per each case, but with the high communicability of Omicron most contact-tracing programs have been <u>eliminated</u> because of infeasibility. Many tens of millions of Americans are exposed to Omicron every week. Unless they are high-risk or have close contact with Vulnerable people, there is no evidence basis for them to follow CDC guidelines.

<u>Vaccines</u> are highly effective against serious disease outcomes, but only modestly effective in preventing infection and transmission.

While we do not have the tools to meaningfully decrease infection, we do have the ability to near-eliminate serious disease. Given the demographics of serious disease, this goal can be met without the necessity of avoiding exposure or infection in the bulk of the Non-Vulnerable population.

FIGURE 2: Percentage of the U.S. population by SARS-CoV-2 infection status, December 2021 and November 2022





PILLAR TWO

Use a binary "high-risk/low-risk" categorization of the population to develop targeted policy recommendations

The risk of serious disease is on a continuous spectrum with the lowest in the young and healthy, and the highest in the oldest and infirm. For policies to be effective, they must be clear, practical, and operationally feasible. This suggests that a necessarily arbitrary binary split between high-risk (the Vulnerable) and lower-risk (the Non-Vulnerable) would enable practical policy development. In absolute numbers, both vaccination and treatment are far more effective in safeguarding Vulnerable people from serious disease than in protecting the Non-Vulnerable populations. The high-risk Vulnerable should be the central policy priority for these interventions.

There are important sub-populations (such as the immunocompromised and health practitioners) who have intermediate levels of risk and who do not naturally fall into this binary schema. They are addressed in Pillar seven.

In the Non-Vulnerable, as avoiding exposure is no longer a realistic, sustainable or desirable goal, pharmaceutical and non-pharmaceutical interventions can be selectively relaxed or eliminated.

In this framework, it is vital to note that Non–Vulnerable populations with regular access to Vulnerable people have a special responsibility to take protective measures seriously.

PILLAR THREE

Unlink the significance and measurement of serious disease (hospitalizations and death) from cases and infections

For a metric to be useful, it should be easily and reliably measurable and directly correlated to performance (in this case to COVID-19 severity and sound policy). "Cases and infections" meet neither criterion while "hospitalizations and deaths" fit both. "Cases" have been a mainstay outcome metric throughout the pandemic-phase, as it

historically reflected levels of community transmission and was essential to align strategies to "flatten the curve" and decrease strain on the health care system. While this metric served its purpose well in the pandemic-phase, it is no longer a constructive metric to track during the current endemic-phase. Some state dashboards have discontinued routine daily case reporting in favor of weekly hospitalization and death surveillance; more will likely follow.

As COVID-19 has evolved, the preponderance of current U.S. testing is no longer laboratory-based but is at-home or other point-of-use rapid testing. Consequently, only about <u>one-in-twenty</u> infections are ever reported, resulting in a diminishing ability to reliably measure and thus leverage cases as a means for understanding COVID-19 outcomes. Further emphasizing this point is the increasing divergence between modeled infections and hospital admissions. Because of the vast underreporting of cases and the lower virulence of current Omicron variants, case counts have become an ineffective indicator of the true health impact of COVID-19. Figure 3 illustrates this divergence, caused by underreported cases and the significantly lower hospitalization rate due to milder Omicron variants:



FIGURE 3: Daily COVID-19 Hospital Census and Estimated Infections



The current endemic-phase features significant unavoidable ongoing community transmission into the indefinite future with periodic case surges. In this phase, only hospitalizations and deaths will provide a valid dashboard signal for the evaluation of COVID-19 health status and of policy impacts.

PILLAR FOUR Prioritize high-risk elderly populations

Elders experience by far the highest rates of serious disease, whether living in healthrelated congregate facilities⁴ (nursing homes and other long-term care facilities/LTC) or living independently. Over the course of the pandemic, they have contributed progressively more to the proportion of total deaths.



FIGURE 4: COVID-19 Deaths by Age Group

Source: Jetelina, "Who Is Dying from COVID-19?" 18 Nov. 2022, based on CDC data

People age 65 and older (elders) represent 17 percent of the population but for the week ending November 30 were responsible for <u>92%</u> of national COVID-19 deaths. Those aged 75 and over are 6.8% of the population but suffered <u>68%</u> of COVID-19 deaths.

The 1.15 million nursing home/skilled nursing facility residents are at by far the highest risk and need the most attention. They have experienced <u>15%</u> of the 1.1 million national deaths to date, yet comprise only <u>0.35%</u> of the U.S. population. Even with the highest age-specific vaccination rates (86.8% have completed primary vaccination and 41% are up-to-date with boosters—having received a bivalent booster), they still account for <u>8%</u> of national deaths and have 45⁵ times the risk of dying from COVID-19 relative to the entire non–nursing home U.S. population. As stark is the nearly 12 times higher death rate of people living in congregate facilities relative to elders living independently.⁵

The <u>14.7</u> million independent-living aged 65 and over contribute approximately 67%⁶ to the national toll of COVID deaths. For comparison, the number of deaths in these elders is <u>97 times</u> higher than the number of deaths among people ages 18–29.

Since the beginning of the pandemic, those living in congregate/LTC facilities have experienced over 150 times the <u>risk of death</u> of all those under age 65.

Hospitalization risk parallels the mortality risk in elders. Those age 65 and older represent over 60% of recent average weekly hospital admissions associated with COVID-19. They have 7 times the <u>risk of hospitalization</u> relative to those under age 65. People 75 and over have 11.5 times the risk compared to the same group.⁷

There are five key policy guidelines to effectively protect the Vulnerable Population. They should:

- be protected from exposure to SARS-CoV-2;
- be up-to-date in primary and booster vaccination series
- have access to testing for early diagnostic confirmation
- have rapid and easy access to oral antivirals, and
- have their public health protection interests prevail, when it intersects with those of the Non-Vulnerable population

Unfortunately, the elderly's current coverage with these life-saving interventions shows significant gaps. Only <u>71%</u> of elders have received a first booster and <u>44%</u> have

received the second. This further reduces to only $\frac{8\%}{100}$ who have received the latest bivalent booster.



FIGURE 5: Weekly COVID-19 associated hospitalizations by age

There are similar underutilization and access issues related to Paxlovid. Although it is <u>highly effective</u> in preventing hospitalization and deaths from Omicron in elders, supply, regulatory, access, and awareness issues have severely curtailed its use in the federal <u>Test-to-Treat</u> program. Utilization data are not available, but in a strategy to approach zero deaths, every elder with symptomatic COVID-19 should have ready access to Paxlovid within three days of the onset of symptoms.

<u>Nursing homes</u> may be state or non-state operated and are subject to regulation by both states and the federal government through the Center for Medicare and Medicaid Services (CMS). This has resulted in a national <u>patchwork</u> of COVID-19 regulations and practices. For example, after district courts blocked the August 2021 federal vaccination mandate, a recent <u>study</u> found great variation in nursing facility staff up to date vaccination levels across all states, with a mean of only 22 percent. <u>CMS</u> has recently issued new enforcement guidance to ensure nursing homes are offering updated COVID-19 vaccines and timely treatment to their residents and staff.

Source: CDC COVID-NET, 11/19/2022

One of the most challenging areas for endemic-phase policy is what to do when the public health interests of the Vulnerable and Non-Vulnerable collide. There are many scenarios—ranging from household, community, school, workplace and public settings where this occurs with regularity. It is beyond the scope of this paper to delve deeply into this area, but it should be a focus of analysis, research and active consideration for the setting of sound policy.

To take one example scenario, millions of Vulnerable and Non-Vulnerable people interact in congregate health facilities. In addition to being vaccinated, people in long-term-care facilities must also be kept safe from imported exposure and infection. This should require special measures for 3 million staff and all visitors: up-to-date vaccination, entrance screening testing, and masking. It is noteworthy in this regard that as of 11/20/2022 less than a quarter of nursing facility staff (22%) were up to date with their vaccinations, a sharp drop from the 87% who completed their primary vaccination series.

Vulnerable people, whether living independently or in congregate settings will need tailored strategies and protocols for protection as society increasingly normalizes. The application of the above five policy guidelines should be based on detailed analysis of the levels of risk involved in various scenarios, and of the characteristics and protection needs of the relevant Vulnerable sub-populations.

This endemic-phase binary schema also has significant policy implications for the much larger Non-Vulnerable population. Although they contribute far less to the serious toll than the smaller Vulnerable population, many additional lives could be saved if Non-Vulnerable people voluntarily used preventive tools. This is especially true when they come into contact with Vulnerable people. While we propose that policy mandates and restrictions for this group should be eliminated, both pharmaceutical and non-pharmaceutical interventions should still be recommended as an individual choice.

Non-Vulnerable people's risk perception will continue to dictate their intent to mask, vaccinate, test, and treat. As with smoking, individual choices will modify personal risk. But the public health impact of these choices does not necessitate restrictions, which could backfire by taking the focus off the Vulnerable Population, who truly do require well-framed mandates and guidelines to mitigate risk.

PILLAR FIVE

Expect seasonal surges and new variants without changing policy-course

It is anticipated that winter behavior changes such as indoor crowding will cause a significant spike in cases. In addition, with a highly mutating virus that already has over 500 circulating sub-variants, we can expect that many <u>new variants</u> and sub-variants with unpredictable characteristics will arise. However, since the emergence of the initial BA.1 Omicron strain spike in February 2022 shown in Figure 6, subsequent Omicron family sub-strains have not resulted in significant changes in weekly deaths. Although no guarantee of a continued trend, this is an observation with encouraging implications for the attenuated virulence of future Omicron evolution.



FIGURE 6: COVID-19 deaths stable across recent Omicron variant waves

<u>Source</u>: Aspinall, Mara G. "Sensitive and Specific" testing newsletter, November 30, 2022

In this environment, the main policy drivers that protect the Vulnerable from serious disease (boosters, Paxlovid) amid the waxing and waning levels of population immunity do not necessitate advance policy changes or excessive "caution". In the event of immune escape or increased severity, policy should be modified to rapidly respond to the actual characteristics of the changing threat.

PILLAR SIX Deal with social trends pragmatically

Polling reveals that <u>79%</u> of the public has returned completely or "somewhat" back to normal. This trend is <u>rising</u> with 65% in November feeling that the COVID situation is getting better compared to 41% in July.

Yet, even with free and generally ready access to life-saving vaccines and treatment, the national trend for uptake has been disappointingly low. This observation is even more evident in the attitudes and practices regarding non-pharmaceutical interventions such as testing, masking, isolation, quarantine, and distancing. Rather than invoke wishful thinking or challenging people's choices, these negative and frequently resistant trends must be factored into endemic-phase COVID-19 policies.

Ending all mandates and restrictions for the Non-Vulnerable Population while recommending and supporting best public health practices, strikes the appropriate balance of societal health and social benefit.

PILLAR SEVEN

Address special sub-populations with customized policies

Several sub-populations may face a higher risk of serious disease, but don't readily fall into this Vulnerable/Non-Vulnerable binary schema. These are healthcare workers, people with <u>CDC-defined</u> medically-significant underlying conditions, the immunocompromised, and those in non-health-related congregate facilities such as prisons and homeless shelters.⁸ Data sets for these groups are typically limited and may

not have standard definitions, population-based studies, systematic federal tracking, or sufficient generalizability to allow translation to policy.

For example, there is little available data on <u>deaths</u> in the country's 22 million healthcare workers since the first year of the pandemic. Similarly, while <u>over 6 million</u> Americans are estimated to be immunocompromised, their <u>serious disease risk</u> is poorly understood.

These are important sub-populations, however, representing all ages that may face a higher risk of serious disease and should be addressed with customized solutions. People in these groups generally have highly individualized risks and circumstances. For now, they are best advised through personal healthcare providers and specific institutional best practices rather than through federal or state guidelines. However, over time and with greater knowledge, some of these groups may become included in the high-risk category. They may not fit into a site-based policy (e.g. skilled nursing facility), but still warrant special clinical guidance and consideration. Healthcare workers could fall under state occupational health guidelines.

PILLAR EIGHT

Optimize both health and socio-economic benefits

The 56 million Americans over age 65 should be the central focus of COVID-19 mitigation, especially the 1.15 million living in nursing facilities. Employing a suite of pharmaceutical and non-pharmaceutical policies and best practices that prioritize this group could decrease serious disease among the Vulnerable population by an estimated 98%². At the same time, given their low risk of serious disease relative to other ambient communicable and non-communicable daily risks, the Non-Vulnerable population can return with "reasonable safety" to normal activities with voluntary pharmaceutical and non-pharmaceutical protections as a personal choice. Where the interests of Vulnerable and Non-Vulnerable popule intersect, the safety of the former should be the primary consideration in policy guidance.

In practice, this means the country can capture simultaneous public health benefits and positive societal impacts. In-person education, commerce, employment, travel, recreation, and entertainment can return to normal, while at the same time serious

disease can be rapidly reduced and eventually approach near zero. Public health benefits need no longer be balanced directly against social, educational, and economic costs.

PILLAR NINE

Incorporate health-equity principles to protect the underserved and people of color in tailored solutions

It is well-established that the underserved and people of color continue to suffer a <u>disproportionate impact</u> of the pandemic toll. This is a result of higher risk from both endogenous (underlying medical conditions) and exogenous (access to care and socio-economic) factors. For the purposes of this endemic-phase policy framework, this group is not considered to be part of the Vulnerable population. However, special attention should be directed at the social determinants of serious disease, in order to diminish the risks and impacts in these specific populations.

PILLAR TEN

Recognize unknowns and uncertainties in scenario planning

Constant change has been a central feature of the novel coronavirus and of the trajectory of the pandemic. As on the battlefield, strategies and actions must be undertaken with limited visibility in an ever-morphing environment. There are many important unknowns and uncertainties that should be recognized and integrated into this new policy architecture.

An established feature of SARS-Cov-2 is its high propensity to mutate and create new variants in response to selection pressure. While current variants have migrated toward greater transmissibility and lower virulence, new variant characteristics may affect transmissibility, virulence, or escape from immune defenses. This uncertainty makes it impossible to accurately predict the future evolution of the virus, to take effective action to prevent the emergence of more dangerous variants, or to gauge the efficacy of prior vaccination series for protection.

Another unknown is how the current cycles of infection and re-infection relate to the specter of long-COVID. With the current, highly communicable Omicron strains, virtually all Americans have had at least one infection. It is not well understood how residual symptoms that occur in 10-30% of those with infections relate to the future risk of development of long-COVID.

The best policy response to these unknowns is not to deviate from the endemic-phase recommendations below. We should proactively develop a research agenda to gain a better understanding of these unknowns. This includes investing in robust genomic detection and disease surveillance as well as in more effective rapid public health response systems. Through these measures, we can accelerate our response to the inevitable real-time evolution of the virus.



Six Policy Recommendations to Protect the Vulnerable and Normalize the Lives of the Non-Vulnerable people

RECOMMENDATION ONE

Tailor booster timing to serious disease risk level

Current FDA and CDC bivalent COVID-19 vaccine guidelines are not age-specific above the age of 18. There is a specific protocol for people who are immunocompromised, but the Vulnerable population as defined here is not distinguished from the population at large. This may explain some of the observed "vaccination fatigue" in Non-Vulnerable people and in the risk-tolerant. At the same time, elders with rapidly-waning immunity—who while being at exponentially greater risk for serious disease—may be inadequately protected from it.

There are three actions needed to maximally protect elders with vaccines:

- Develop more risk-focused vaccine guidelines tailored to protect Vulnerable populations separately from the general population. More emphasis should be placed on absolute risk-reduction and less on relative risk-reduction, as the former will likely distinguish the groups at greatest benefit. A consideration of where NNI (number needed to immunize to prevent a hospitalization) is highest.
- Base booster interval guidelines on vaccine efficacy durability studies in highrisk people and make conservative assumptions to err on the side of safety.
- Prioritize efforts to increase vaccine confidence and uptake in those who will benefit the most. (<u>Recently announced</u> major grants through the Department of Health and Human Services focusing on reaching the elderly through paid media

and making vaccination more convenient represent a significant step in the right direction).



FIGURE 7: COVID-19-Associated In-Hospital Deaths by Age Group and **Vaccination Status**

Source: Jetelina, "Who Is Dying from COVID-19?" 18 Nov. 2022, based on CDC data

RECOMMENDATION TWO

Facilitate rapid therapeutic access and use of oral antivirals (Paxlovid) for the Vulnerable population

Paxlovid has been available since December 2021 as an FDA-approved life-saving oral treatment that reduces the <u>risk</u> of death in elders—regardless of vaccination status—by <u>46-88%</u>. Recent data shows that Paxlovid (and other oral antivirals such as Lagevrio and Veklury) are greatly underutilized, especially in the elder population who stand to benefit the most.



FIGURE 8: Receipt of COVID-19 Treatments by Age Group

Source: Jetelina, "Who Is Dying from COVID-19?" 18 Nov. 2022, based on CDC data

There are many gaps that should be addressed to enhance Paxlovid use. The foremost is to prescribe and dispense it preventively to elders at home or at point of use, so waittime can be reduced in the event of a positive test. This should be accompanied by appropriate direct-to-consumer education materials as well as rapid antigen tests to facilitate point-of-use diagnosis. Those without contraindications should have it readily available at the onset of proven symptomatic COVID-19 infection. In magnitude of impact, this may be the single most important policy change to bring down national deaths.

RECOMMENDATION THREE

Develop "fit-for-purpose" new use cases for rapid testing

To significantly decrease the pandemic toll, rapid testing must be deployed in innovative new ways. This calls for a significant revision to the current CDC <u>testing guidelines</u> and related White House <u>policy</u>. Diagnostic testing is currently still recommended for all persons with symptoms and with known or suspected exposure. Similarly, screening testing strategies still apply to "all persons, irrespective of vaccination status."

Rapid tests' favorable <u>performance characteristics</u> should now be applied only to the focused goal of preventing serious disease in Vulnerable people. The new indication for rapid testing should invoke a single firm criterion: "will the test result dictate a new course of action that decreases the risk of serious disease in high-risk persons?" Testing should be indicated only when the answer is "yes."

A few initial scenarios that fulfill this criterion:

- When exposed, asymptomatic high-risk people test positive, they should be isolated from other vulnerable people and monitored for symptoms
- When symptomatic, high-risk people test positive they should be provided treatment to decrease the severity of the illness (called Test-to-Treat)
- To decrease the risk of exposure, close contacts with high-risk people, both household or institutional, are candidates for self or entrance testing (in addition to vaccination).

These use cases provide benefits that exceed individual and societal costs only to those at high-risk and their close contacts.

The CDC should be tasked with reviewing the evidence-basis of testing guidelines and protocols for the above use cases to protect Vulnerable people. The new guidelines could be more efficient in our testing strategies, especially those provided through payers and the government. These guidelines could *eliminate* most recommended testing in the approximately 276 million non-high-risk Americans. At the same time, the nation could greatly *increase* testing to protect the high-risk groups, in which the risk-benefit balance is more favorable to both individuals and society. This should result in dramatic declines in hospitalization and deaths through the application of life-saving targeted interventions.

One potential outcome of a science review is that rapid testing may no longer be advised in circumstances involving Non-Vulnerable people where the results do not imply actions. This could include most at-home symptomatic or asymptomatic diagnostic testing, school, college, or workplace screening including test-to-stay programs, border entry, and contact identification and tracing.

RECOMMENDATION FOUR

Eliminate restrictions in Non-Vulnerable people and Institutions

The CDC has progressively relaxed but not eliminated testing-associated isolation, quarantine, masking, and international entry guidelines. Its recent <u>recommendations</u> and most official <u>federal policy</u>—although prioritizing the protection of people at high risk of death—are still based on the putative benefit of avoidance of exposure and infection by everyone. This results in confusing public and professional mixed messages.

For the Non-Vulnerable population, influenza (the "flu") and other respiratory infections may serve as a societal model for rational guidance and behavior. While the government need not continue to regulate the movement of people, they should still be educated and advised on when and how to minimize infecting others when sick with fever and cough.

Until policies are clearly centered on the assumption that Non-Vulnerable people can be exposed to COVID-19 with a similar risk profile as to other ambient respiratory pathogens, our educational, cultural, workplace, and social institutions will be mired in confusion, conflict, and controversy. There is no longer a sufficient evidence-based rationale for policies that perpetuate the strict avoidance of exposure in the Non-Vulnerable population.

RECOMMENDATION FIVE

Make national COVID-19 coding of "serious disease" reporting valid and consistent

Because of coding and reporting irregularities, only <u>some states</u> have the capacity to distinguish whether COVID-19 is the cause or an incidental positive test in association with hospitalizations and deaths. This is an important distinction when <u>studies</u> have estimated that only about 50% of hospitalizations with COVID-19 are caused by the virus. To make sound public health decisions we need a national dashboard with instrumentation that can reliably guide us. The CDC should be given authority to design and implement this dashboard through standardized state reporting of COVID-19 to federal authorities.

RECOMMENDATION SIX

Roll out parallel "living with the virus" public education program to address Non-Vulnerable and Vulnerable population key messages.

For much of the country, the three-year course of the pandemic has been a harrowing roller-coaster ride. A main feature has been constant change in information, individual risk perception and tolerance, media coverage, and a shifting pandemic-phase policy response. There has been polarization and controversy around what the science says, and what responsible people should do to protect themselves and each other. This schism has frequently been refracted through a partisan political and ideological lens.

The endemic-phase policy recommendations presented here cut across politics and can pull the country closer together. They feature a re-interpretation of the science that can both drive down the toll and re-open society. To achieve this goal, it is essential to deploy a parallel public education program that supports policy-driven information affecting both Vulnerable and Non-Vulnerable groups. Many of the Non-Vulnerable population has spent the last three years strenuously avoiding exposure and infection. Through lockdowns, masking, testing, vaccination, social-gatherings and school-reopening controversies, they steadfastly engaged in transmission-limiting practices. For this third of the population, the psychology of transitioning from an "avoid exposure" to a "living-with-the-virus," *do-not-fear-exposure* paradigm is daunting and fraught. These Americans are still very concerned about the pandemic and do not think they can return to their normal lives anytime soon.

FIGURE 9: Americans living in different pandemic worlds



<u>Source</u>: Axios-Ipsos poll: Jackson, Newall, Diamond, Duran, Rollason, "Americans are moving on from COVID-19 despite acknowledged risks", 19 July 2022.

This is the most confused and conflicted group facing the uncharted adaptation from pandemic to endemic-phase practices. They need common-sense guidance (e.g. do I test, mask, travel?), strategic messaging, support and reassurance to navigate their passage to the new normal with mental and physical security.

Vulnerable people should understand that they are not subject to discrimination because of age, infirmities or domicile, but that their recommended safeguards are a consequence of hugely increased risk because of weakened immune systems and difficult-to-avoid exposure. Interventions that are personal options for others are lifepreservers for them.

COVID-19 exposure will never be entirely free of risk of infection or illness. But how this compares to commonly encountered communicable disease risks (eg. flu, pneumonia, Respiratory Syncytial Virus) or other daily risks (e.g., motor vehicle accidents, drowning, homicides) may help people make more sound personal decisions. Sophisticated messaging and communication strategies should accompany an endemic-phase paradigm-shift campaign of "living safely with exposure."

Reaching the Goal of Near-Zero Deaths

We estimated the impact of the recommended suite of new policies assuming complete coverage of the prioritized sub-populations. This is a hypothetical exercise to determine whether the national goal of near-zero deaths (and proportional hospitalization declines) is realistically achievable.

The two major life-saving interventions of the endemic-phase are up-to-date vaccination and Paxlovid coverage for elders. Deaths averted is the hypothetical calculation of the proportionate increase to full coverage of each intervention, times the expected benefit of percentage of lives saved.

Applying this formula, with up-to-date vaccine coverage, the 56 million Vulnerable Population would see an about 89%² reduction in serious disease. Additionally, Paxlovid has been shown to reduce the risk of death by 79% in people aged 65 and older. A conservative assumption is that only ~10% of eligible elders are "covered" with Paxlovid (have taken Paxlovid within three days of onset of symptoms) and 8% with up-to-date vaccination. Extending to full coverage by combining both interventions would avert nearly 98%² of new deaths in the elderly. On a national basis, this would decrease the current 7-day rolling average of ~320 deaths to ~83 deaths, which represents a 74%² reduction in deaths across all Americans.

A similar <u>efficacy factor</u> calculation of full coverage with vaccination and Paxlovid applied to hospitalizations, projects a 93% reduction from 1,330 to 87 per week in those age 65 and over. This represents an 53%¹ reduction in hospitalizations across all Americans.

Conclusion

As the expected winter "trifecta" of respiratory disease surges arrive (COVID-19, RSV, Infuenza), the Biden Administration needs to act urgently on its <u>promise</u> that "when properly used, the tools we now have can prevent nearly all COVID deaths."

Over <u>four-fifths</u> of Americans support free federal government programs for at-home tests, treatments, and vaccination. Ensuring easy, equitable access to these life-saving interventions, however, is necessary but not sufficient. A more effective solution is a course correction in our COVID-19 policy: a strategic national "living with the virus" program with updated guidelines, protocols, and public education that fully protects our

high-risk population (the Vulnerable) and support the return to normal for everyone else (the Non-Vulnerable). This is the key to fully returning the country to its dynamic, robust pre-COVID-19 state.

As the nation moves through the most disruptive pandemic in our history and enters a new phase, it can take actions to simultaneously safeguard public health and protect individual freedom. Now is the time for a reset.

Endnotes

¹According to the <u>CDC</u>, current 6-month weekly average hospitalizations (both vaccinated and unvaccinated) are as follows.

- <65 population = 1,077
- 65+ population = 1,330
 - <u>CDC</u> reports that 8 out of 9 hospitalizations are from unvaccinated or partially vaccinated individuals
 - (8/9) * 1,330 = 1,182 hospitalizations of the 65+ population that are preventable with the protocols outlined in this paper

For the 65+ population, the CDC states that full vaccination is <u>94%</u> effective at reducing hospitalizations.

Assuming the preventable population becomes fully vaccinated...

- 94% * 1,182 = 1,111 hospitalizations saved if fully vaccinated
- This results in 71 hospitalizations of the 65+ preventable population that are unaffected by full vaccination

Now we want to understand how Paxlovid could benefit the remaining 65+ population.

- 1,330 1,182 = 148 hospitalizations from fully vaccinated 65+
- 71 hospitalizations (carry from above)
- 148 + 71 = 219

The New England Journal of Medicine reports that Paxlovid has a <u>75%</u> reduction in hospitalizations. So...

- 75% * 219 = 164 hospitalizations saved with Paxlovid distribution
- 219 164 = 55 unpreventable hospitalizations within the 65+ population, which is a 96% reduction in hospitalizations among the 65+ population

Thus, if the protocols outlined in this paper are effectively implemented, the new 6 – month weekly average hospitalizations (both vaccinated and unvaccinated) are as follows.

- <65 population = 1,077
- 65+ population = 55
- Total = 1,132 (53% reduction)

²Receipt of the second booster is <u>90%</u> effective in preventing death alone. Only <u>44%</u> of the elderly have a second booster. In Washington, unvaccinated elderly are 4.5 times more likely to die from COVID-19, equating to <u>81.8%</u> of the deaths among the elderly are from unvaccinated people.

Combining the three above resources...

Deaths of elderly from covid...

- 8% have the bivalent booster, implying that 92% have not received it
- 82% of deaths are from people who are unvaccinated, implying that the remainder of deaths (18%) are partially or fully vaccinated
- So, 92% of remaining 18% of deaths are not fully vaccinated (one booster)
- Resulting in a total 82% + 16.56%= 98.56% of covid deaths among elderly were either unvaccinated or not fully vaccinated

If the bivalent booster is assumed to have equivalent efficacy at preventing death as previous boosters (90%) then...

• 90% * 98.56% = 88.7% of deaths among 65+ population are preventable

Current 7-day average daily COVID death count = 320

- Elderly make up approximately 75% of deaths due to COVID, resulting in 75% * 320 = 242.4 daily deaths among 65+ population
- At 88.7% preventable deaths, 242.4 reduces down to just 27.39 deaths due to COVID among the 65+ population

With the 27.39 residual deaths among the 65+ population, the introduction of Paxlovid has the opportunity to further reduce this number.

- Assuming all 27.39 individuals would qualify for, be prescribed, and take Paxlovid, and a 79% efficacy at preventing death...
- 79% * 27.39 deaths = 21.64 preventable deaths
- This leaves 5.75 deaths due to COVID-19 among the 65+ population that are not preventable with boosters or Paxlovid

• This equates to a 98% reduction in deaths for the 65+ population – (242.4 – 5.75) / 242.4

Recalculating the new 7-day average becomes 77.6 deaths from <65 population plus the 5.75 residual deaths from the 65+ population resulting in a new 7-day average of 83.35 deaths. This equates to a 74% reduction of the current 320 7-day average deaths due to COVID-19.

³According to the CDC's COVID-19 <u>death counts</u>...

- Total deaths in November = 5,095
- <65 population accounted for 8% of these deaths = 407.6
 - With a population of 275.9M, this equates to 0.00015%
- 65+ accounted for 4,687.4
 - With a population of 56M, this equates to 0.00837%

Thus, the relative risk of 65+ to <65 is 0.00837% / 0.00015% = 56.6

⁴Health-related congregate facilities refers to facilities that report to the CDC's National Healthcare Safety Network (NHSN) Long Term Care Facility (LTCF). Thse include nursing homes, skilled nursing, chronic care, and Intermediate Care Facilities for individuals with Intellectual disability (ICF/ID). For simplicity, and to align with <u>CMS</u> language from which the data was derived, "nursing homes" is used throughout the article.

⁵Relative risk of death of nursing home residents compared to non-nursing home residents is calculated by comparing the ratios of nursing home COVID-19 deaths all time divided by the nursing home population and non-nursing home deaths all time divided by the non-nursing home population

- Nursing home ratio: 157,692 / 1,157,714 = 13.6%
- Non-nursing home ratio (all ages): 879,440 / 330.7M = 0.3%
- Relative risk: 13.6 / 0.3 = 45.3x

Similarly, we can compare the relative risk of 65+ nursing home residents versus 65+ non-nursing home residents.

• Nursing home ratio: 157,692 / 1,157,714 = 13.6%

- Non-nursing home ratio (65+): 632,776 / 54,842,286 = 1.15%
- Relative risk: 13.6 / 1.15 = 11.8x

⁶CDC, CMS

⁷According to the <u>CDC</u>, the 6-month average weekly hospitalization rate per 100,000 individuals for select groups is as follows.

- <65 population = 3.9
- 65+ population = 26.9
- 75+ population = 45.0

Cacluating the risk relative to the <65 population is as follows.

- 65+ population = 26.9 / 3.9 = 6.86
- 75+ population = 45.0 / 3.9 = 11.48

⁸Immunocompromised

- Definition: <u>Individuals</u> with a compromised or weakened immune system because of a medical condition or a treatment for a condition.
- Estimated Population: 6,638,000 (estimated <u>2%</u> of <u>population</u>)
- Estimated COVID Deaths: Data Unavailable
- Risk of COVID Death (unvaccinated): adjusted odds ratio = <u>1.34</u>
- Risk of COVID Death (vaccinated): adjusted odds ratio = <u>1.87</u>

Prisoners

- Definition: Incarcerated people in state and federal prisons
- Estimated Population: <u>2 million</u>
- Estimated COVID Deaths: <u>3,000</u>
- Risk of COVID Death: 0.15%

Homeless

• Definition: A person without a home, and therefore typically living on the streets

- Estimated Population: <u>580,466</u>
- Estimated COVID Deaths: <u>633</u>
- Risk of COVID Death: 0.11%

Healthcare Workers

- Definition: One who delivers care and services to the sick and ailing either directly as doctors and nurses or indirectly as aides, helpers, laboratory technicians, or even medical waste handlers.
- Estimated Population: <u>22 million</u>
- Estimated COVID Deaths: Data Unavailable
- Risk of COVID Death: Data Unavailable