

JOSH GREEN, M.D. GOVERNOR KE KIA'ĀINA

May 19, 2025

U.S. Senate Committee on Homeland Security & Governmental Affairs Permanent Subcommittee on Investigations 340 Dirksen Senate Office Building Washington, DC, 20510

Chairman Johnson, Ranking Member Blumenthal, and Members of the Subcommittee:

Thank you for the opportunity to appear before you today. My name is Josh Green, and I currently serve as the Governor of the State of Hawai'i. I am also a physician who has practiced both family and emergency medicine for over 20 years, primarily serving rural and underserved communities. I earned my undergraduate degree from Swarthmore College and my medical degree from the Penn State College of Medicine. In 2000, I moved to Hawai'i through the National Health Service Corps and began work at a rural clinic on the Big Island. That experience continues to shape my approach to healthcare and public service.

I appear before you today to reaffirm what the overwhelming majority of scientific and medical experts have confirmed: COVID-19 vaccines are safe, effective, and have saved millions of lives in the United States and around the world.

As a physician and as Governor, I have seen firsthand how access to preventive medicine, accurate health information, and community trust in science can save lives. I have also seen how the absence of those things can lead to tragedy. That truth is deeply woven into Hawai'i's history.

After first Western contact in 1778, infectious disease decimated the Native Hawaiian population. At the time, there were estimated to be more than 600,000 Native Hawaiians living across the islands. Within just over a century, that number had dropped to fewer than 40,000. The causes were not war or famine. They were diseases such as measles, smallpox, influenza, and whooping cough. These were illnesses for which Native Hawaiians had no natural immunity, and which spread rapidly in the absence of vaccines or effective treatments. Entire communities were wiped out. The cultural trauma of that loss is still felt today. It is precisely why many in Hawai'i, especially Native Hawaiian leaders and elders, understand how dangerous infectious disease can be and why they have supported vaccination efforts to protect future generations.

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That historical understanding shaped our response to two modern public health crises I was directly involved in: the 2019 measles outbreak in Samoa and the COVID-19 pandemic.

In late 2019, while serving as Hawaiʻi's Lieutenant Governor, I helped coordinate a rapid medical response to a deadly measles epidemic in Samoa. Vaccination rates had collapsed following waves of misinformation, much of it driven by online anti-vaccine rhetoric. Within 48 hours of a formal request, we mobilized more than 70 volunteer physicians and nurses and secured thousands of vaccine doses. In just two days, we vaccinated tens of thousands of residents. But the human toll was devastating. Eighty-three lives were lost, most of them children. I will never forget arriving at one home just minutes after a toddler had died in her parents' arms. Her death, like so many others, was preventable. But medicine had arrived too late to outrun misinformation.

That experience was fresh in my mind when COVID-19 reached our islands. As Lieutenant Governor, I served as the state's COVID-19 response coordinator. My role included overseeing testing, vaccination, and statewide public health strategy. From the beginning, we prioritized science, transparency, and culturally rooted outreach. We partnered with Native Hawaiian and Pacific Islander leaders, trusted messengers, and local clinics to ensure communities most at risk had accurate information and equitable access to care.

In fact, as COVID liaison, I worked closely with President Trump's administration to help secure and distribute vaccines as they became available in late 2020. That coordination was essential to ensuring that Hawai'i, despite its geographic isolation, received timely access to the first wave of vaccinations. This collaboration helped protect our healthcare workers, the elderly, and vulnerable populations during a critical window.

At the same time, we stood up one of the most innovative pandemic mitigation tools in the country: Hawai'i's Safe Travels program. This initiative, which required incoming travelers to undergo pre-travel testing and screening, allowed us to safely reopen our tourism economy while keeping infection rates under control. Tourism is the single largest driver of Hawai'i's economy, and Safe Travels was vital to avoiding prolonged shutdowns. The program kept our hospitals from being overwhelmed, allowed local businesses to recover more quickly, and delivered an extraordinary return on investment—preserving billions of dollars in economic activity and state revenue during one of the most challenging periods in our history. It also became a national model for balancing public health with economic survival.

When vaccines became available, Hawai'i launched one of the most aggressive and inclusive campaigns in the country. According to data from Johns Hopkins University, Hawai'i achieved one of the lowest per capita COVID-19 case and death rates in the nation and one of the highest vaccination rates. These outcomes were not an accident. They were the result of early, science-based action and collaboration across sectors.

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I want to be very clear: the federal vaccine safety system is among the most robust in the world. It includes multiple complementary tools such as VAERS (the Vaccine Adverse Event Reporting System), V-safe, and the Vaccine Safety Datalink. These systems are designed to monitor, identify, and transparently report possible side effects. When rare cases of myocarditis emerged, particularly among young males following mRNA vaccination, the system functioned exactly as intended. The data were made public, warnings were updated, and clinical guidance was revised accordingly.

Despite this, some continue to promote misleading interpretations, unverified claims, or anecdotes to suggest that vaccines are broadly unsafe. These assertions are not supported by peer-reviewed research or the global scientific consensus. In fact, studies show that the risk of myocarditis is significantly higher after COVID-19 infection than after vaccination. When vaccine-related myocarditis does occur, it is generally mild and treatable.

Vaccines have protected our most vulnerable: children, pregnant individuals, the elderly, and those with chronic illnesses. They have dramatically reduced hospitalizations and saved countless lives.

Science is not perfect. But it is transparent, self-correcting, and grounded in evidence. We owe it to the American people to reject fear-driven narratives and instead support policies rooted in facts, especially when the health and safety of our communities are at stake. Public health must remain above politics. When science is politicized, trust erodes, and lives are put at risk. We cannot allow ideology to dictate our response to future health crises.

I am proud of how Hawai'i responded to this crisis. I am proud of our healthcare workers, our community leaders, and our people who chose facts over fear and action over division. But we must remain vigilant. The next outbreak, the next disinformation campaign, the next test of our resilience is coming. We simply do not know when.

Thank you again for the opportunity to testify. I welcome your questions and hope Hawai'i's experience can offer some guidance as we work to build a healthier, safer future for all.

Mahalo,

Josh Green, M.D.

Governor, State of Hawai'i

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The New Hork Times

https://www.nytimes.com/2025/01/07/opinion/rfk-samoa-hawaiigovernor.html

GUEST ESSAY

I'm the Governor of Hawaii. I've Seen What Vaccine Skepticism Can Do.

Jan. 7, 2025



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By Josh Green

Dr. Green is the governor of Hawaii.

In early December 2019, I called Faimalotoa Kika Stowers, the health minister of Samoa. The measles outbreak that began earlier that fall on her small Pacific island nation had spread out of control and become an epidemic that threatened to overwhelm the country. The deep bond Hawaii shares with Samoa meant this was a shared crisis. As the lieutenant governor of Hawaii at the time and a practicing physician, I knew we needed to act quickly to save lives.

Almost 20 years earlier, I arrived on Hawaii's Big Island as part of the National Health Service Corps to practice medicine at a small clinic in a remote community. I learned the value of preventive health care for rural, low-income patients, and the essential fact that vaccines are one of the most effective tools we have to prevent illness and save lives, especially those of children. As a rule, keeping vaccination rates above 95 percent can protect an entire population from infectious diseases like measles.

But when vaccination rates fall, preventable diseases can regain a foothold and pose a new danger. And that's precisely what happened in Samoa, after misinformation spread by anti-vaccine activists eroded trust in vaccines and led to the 2019 outbreak. Thousands of preventable cases of measles sprang up, leading to the deaths of 83 people, mostly children. One of the most prominent voices behind the anti-vaccine campaign was Robert F. Kennedy Jr.

Vaccines and public health vaccination programs are not just medical interventions; they are also moral imperatives. They embody our commitment to saving lives, ending disease and protecting the health and well-being of future generations. If Mr. Kennedy is confirmed as secretary of the Department of Health and Human Services under Donald Trump and serves as our nation's chief health care officer, there is a real danger that he will continue to spread doubt and misinformation, potentially causing vaccination rates to fall and leading to more preventable deaths. America can't allow that to happen.

The tragedy in Samoa five years ago shows not just how lower vaccination rates can lead to a public health crisis but also how renewed vaccination campaigns can end such crises. I recall offering Ms. Stowers our immediate assistance, pledging five doctors from Hawaii and 5,000 doses of the measles vaccine. She asked if we could do more.

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Within 48 hours, we assembled an extraordinary emergency medical team of about 75 volunteer nurses and doctors to fly to Samoa. Organizations such as UNICEF and the Health Care Association of Hawaii provided essential medical supplies, including vaccines. The team's willingness to drop everything to help a neighboring Pacific nation was nothing short of extraordinary.

Our plane landed in Samoa on Dec. 4, 2019, first thing in the morning. Over the next day and a half, alongside a few hundred Samoan health care workers, our team traveled from village to village and vaccinated tens of thousands of people. By the time our plane took off for Hawaii the next afternoon, we had helped curb the measles epidemic. Health data released later that month showed a significant decline in cases, the result of Samoa's vaccination rate reaching 95 percent.

But we also witnessed the deadly consequences of the anti-vaccine campaign. We arrived at one home just minutes after a toddler girl had died from measles, her mother bursting into tears as we approached. The child was lying on a makeshift bed in the middle of the family's one-room house, her face still red from fever. I put my hands on her face and could feel the warmth in her skin, but her eyes were fixed and glazed over. My stethoscope confirmed she was no longer breathing.

In spite of her severe case of measles, her family was caring for her at home because the hospital was filled beyond capacity and there weren't enough doctors, nurses or beds to accommodate her. We shared a moment of mourning for her with her parents and then proceeded to vaccinate her family members at the parents' request before we had to move on to continue our mission.

The measles epidemic in Samoa was a heartbreaking example of how quickly things can go wrong when vaccination rates are allowed to fall. A tragic human error in 2018 involving improperly prepared vaccines led to the deaths of two local infants, shaking public confidence. Though the vaccine was confirmed to be safe, many parents became hesitant to immunize their children.

Mr. Kennedy and others fanned the flames of this fear with misinformation. The people of Samoa shared with me that they got very little news from outside their community but that in the months before the 2019 epidemic they were bombarded with social media posts claiming that vaccinations were unsafe and would harm or even kill their children. Activists from other countries, including Mr. Kennedy, claimed vaccines were dangerous. Many Samoans were afraid to vaccinate their children, and by late 2019, the epidemic was raging, overwhelming Samoa's national health care system.

The experience in Samoa was fresh in my mind when the Covid-19 pandemic reached Hawaii in early 2020. As lieutenant governor, I took on the responsibility of keeping our people informed with constant updates and factual information. That steadfast approach continued when the Covid-19 vaccine became available and anti-vaccine propaganda continued to spread rapidly online. Hawaii's vaccination rate was among the nation's highest and its mortality rate among the lowest, saving thousands of lives in our state. Like our emergency medical mission to Samoa, Hawaii's Covid response was a testament to what we can achieve when our public health efforts are ambitious and based in scientific fact.

Vaccination programs are one of the greatest public health achievements in human history. Vaccines have saved more than 150 million lives over the past 50 years and cut infant mortality by 40 percent worldwide. Because of international vaccination programs, we have eradicated smallpox and reduced polio cases by more than 99 percent. The measles vaccine alone has saved an estimated 94 million lives globally since 1974, virtually eliminating the disease in the United States since 2000.

Yet, despite the overwhelming evidence for their safety and the record of their lifesaving power over the past 50 years, figures such as Mr. Kennedy continue to spread misinformation about vaccines. In a podcast appearance in 2023, he claimed that "there's no vaccine that is safe and effective." This is false. Such talk is reckless and dangerous. I saw this in Samoa.

As we look to the future, the possibility of his being confirmed as the secretary of health and human services is cause for grave concern. I worry he would jeopardize half a century of progress and success gained by the United States as a result of vaccination programs. Too much depends on our commitment to truth and the lifesaving power of vaccines to entrust Mr. Kennedy with the direction of these programs. Our children's lives depend on it.

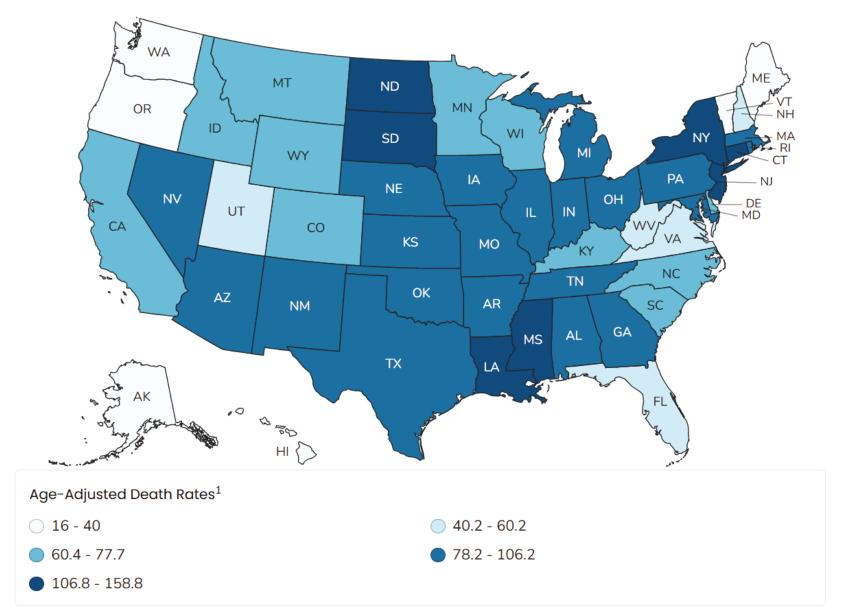
Josh Green, a Democrat, is the governor of Hawaii and a physician.

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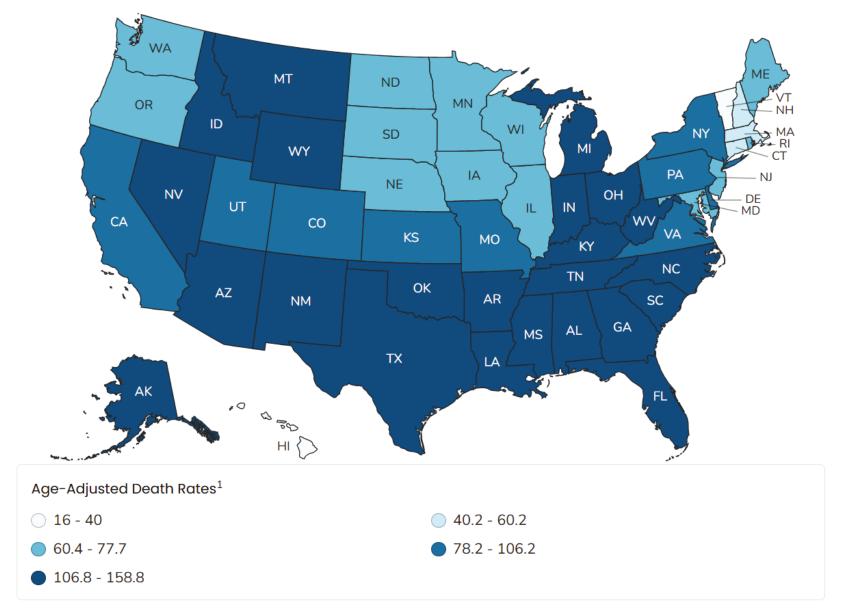
A version of this article appears in print on , Section A, Page 18 of the New York edition with the headline: I've Seen What Vaccine Skepticism Can Do

2020 COVID-19 Age-Adjusted Deaths Per 100,000 Population, by State



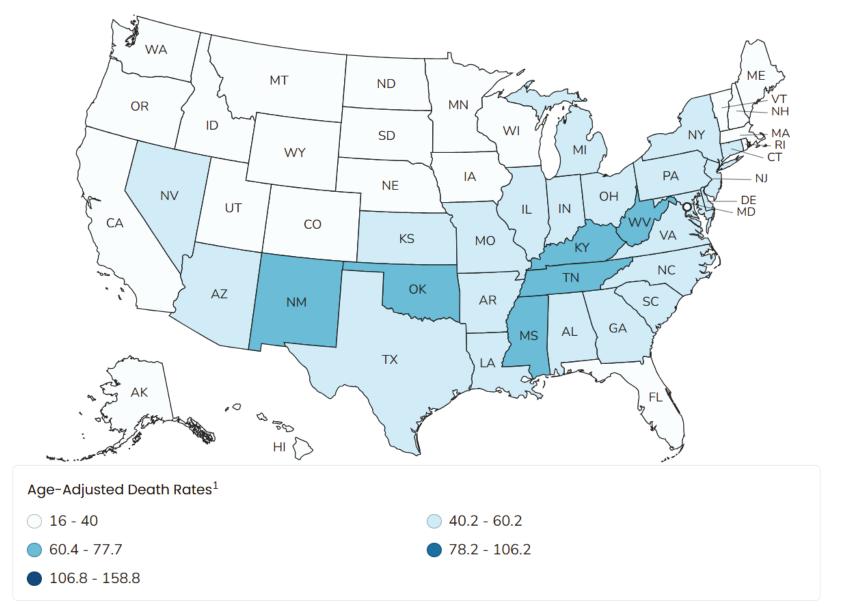
Top 10 States				
ath Rates				
Death Rate				
16.0				
16.8				
20.2				
26.0				
35.7				
36.7				
40.9				
48.6				
56.2				
56.3				

2021 COVID-19 Age-Adjusted Deaths Per 100,000 Population, by State



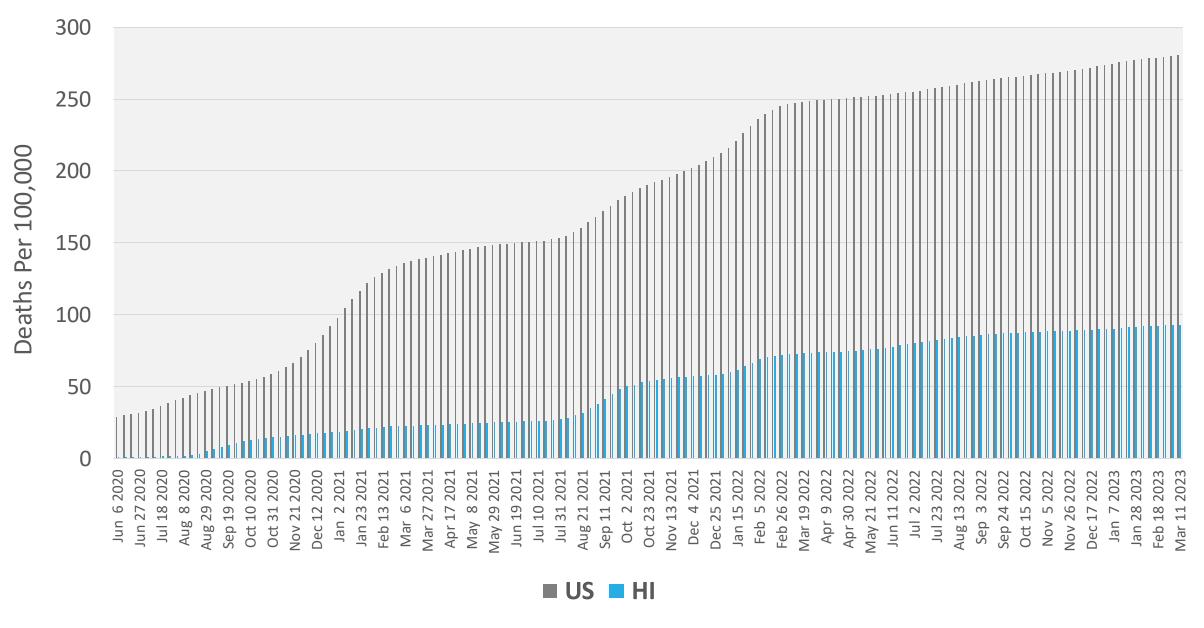
Top 10 States					
with Lowest Dea	ath Rates				
State	Death Rate				
Vermont	29.5				
Hawaii	36.5				
Massachusetts	54.6				
Connecticut	56.7				
New Hampshire	60.2				
Washington	61.5				
Minnesota	64.1				
Maine	66.2				
Rhode Island	66.4				
Nebraska	69.0				

2022 COVID-19 Age-Adjusted Deaths Per 100,000 Population, by State

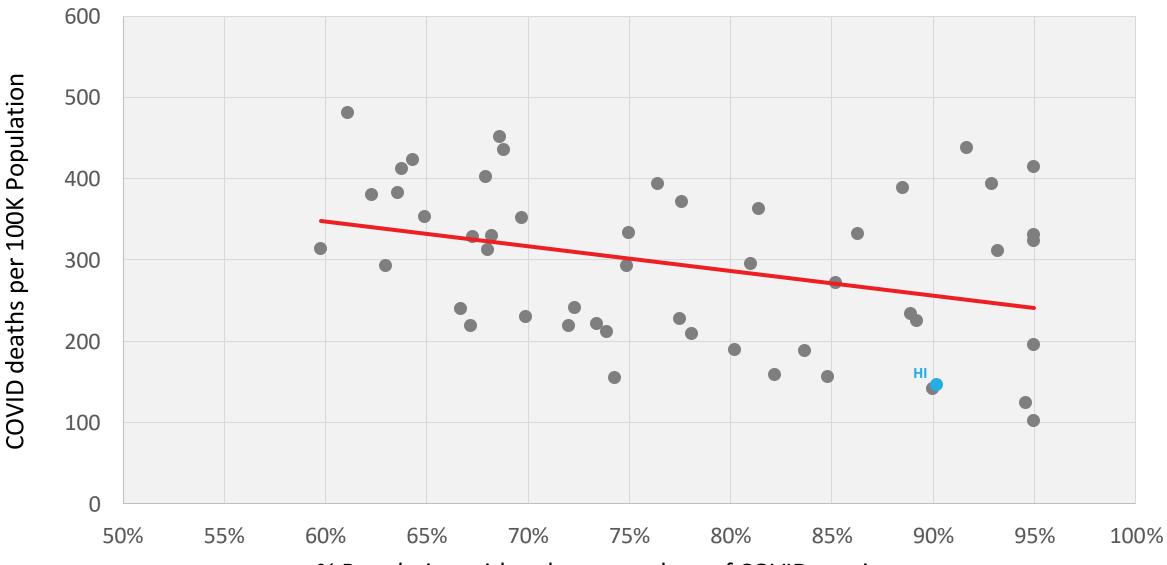


Top 10 States					
ath Rates					
Death Rate					
20.3					
25.2					
30.3					
31.3					
31.6					
33.1					
33.3					
33.6					
34.0					
34.1					

Total Deaths Per 100,000 Population (age-adjusted)

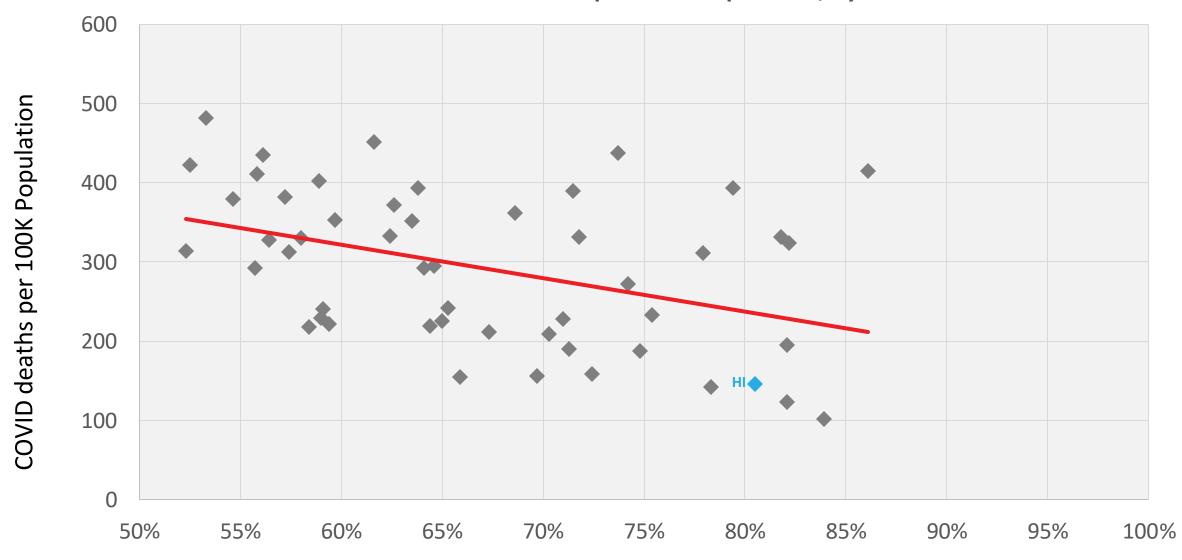


Association Between % Population with at Least One dose COVID Vaccine and COVID Deaths per 100K Population, by State



% Population with at least one dose of COVID vaccine

Association Between % Population Fully Vaccinated with COVID Vaccine and COVID Deaths per 100K Population, by State



% Population fully vaccinated with COVID vaccine

FINAL REPORT

Surveillance of COVID-19 Infection in Pre-tested Travelers to Hawaii

November 30, 2020

Author

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Without Whom This Project Would Not Have Been Possible

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Summary

The Hawaii Safe Travels program results in an estimated 1 to 2 parts (SARS-CoV-2 infection) per 1,000 arrivals. Infection rates at departure locations increased during the surveillance period. The overall state estimate based on DOH results of 345,788 arrivals during the study period, was 0.6536 infections per 1,000 arrivals. Recommendations for improving the Hawaii Safe Travels program are included.

"So far, the (Safe Travels) program is working and with a few enhancements, the committee believes it can be improved upon and some of the confusion about the program can be eliminated", House Speaker Scott K. Saiki said in a statement." *Star Advertiser* 12/1/2020. B1

Study Abstract

Starting on Oct 15, 2020, the State of Hawaii reopened to travelers from the US Mainland. For travelers to avoid a 14-day quarantine in Hawaii, a nasopharyngeal negative RT-PCR test for SARS-CoV-2 (the virus that causes COVID-19) or other NAAT (Nucleic Acid Amplification Test) from a certified provider within 72 hours prior to disembarking was required. The passengers also had to be free of COVID-19 symptoms.

This plan to safely reopen Hawaii to travel and avoid or minimize additional introduction of virus by potentially infected visitors or returning residents was proposed in an UHERO document published in June, 2020².

This report is an independent epidemiological evaluation of the UHERO proposal. Briefly, any individual planning to travel to Hawaii from the US Mainland would have to complete the self-screen (as described on the Safe Travels Website) and have a negative NAAT results in a 72-hour period prior to departure.

The study or evaluation of this plan, <u>in short</u>, was to retest selected traveler again after arrival in Hawaii. Retest could be taken on arrival or up to 4 days after arrival. A sketch of this plan is given below:

Screen > 72hours > NAAT Test > Arrival > x days > Re-Test

The study design is simple: how many re-tests of a negative Screen > 72hours > NAAT Test, would be truly positive? This is a test of NAAT sensitivity based on a follow-up re-test.

Conceptually, this could have been carried out without travel and at any location.

A second level of empirical evaluation was conducted at the aggregate or ecologic level, which is a collective evaluation of the testing and the overall Safe Travels program implementation, in effect, an evaluation of a public health intervention.

An important objective of the investigation was to present, at the end of study, an epidemiologically valid and unbiased result on which state decision makers could make rational, justifiable, decisions.

Noting that the magnitude of accuracy or test sensitivity or lack thereof, to be considered acceptable to the community in Hawaii, is a subjective decision and a matter of practicality given potential economic consequences. Interpretations of the results are given but recommendations regarding travel to Hawaii are not.

A brief pilot phase was initiated on October 19, 2020, followed approximately two weeks later with a more complete implementation. Numerous logistical issues beyond the control of this project required various modifications. Initially the project was planned to be completed by the end of the year.

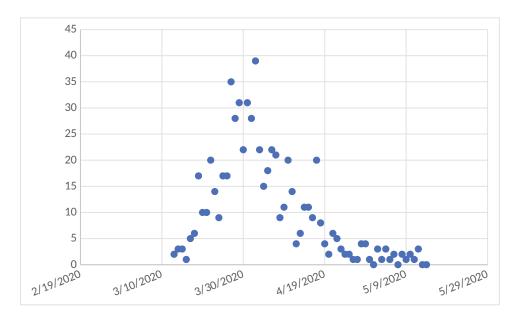
Additional information on the study design, changes in study design during the pilot phase, and related details are provided in the body of the report.

INTRODUCITON

SARS-CoV-2 and COVID-19 in Hawaii

The Wuhan outbreak: Wuhan is the capital of Hubei Province in the People's Republic of China. It is the largest city in Hubei and the most populous. The origin of the SARS-CoV-2 (the virus that causes COVID-19 infection) was traced to Wuhan in late December 2019. Vision Medicals first sequenced the new virus and by January 2020, the genomic sequence had been posted on the web worldwide. With that information, any university microbiology laboratory would be able test for the presences of the virus¹.

The first cases of COVID-19 in Hawaii were reported on March 13, 2020. **Figure 1** below shows the first peak of cases in March (during which travel to Hawaii was restricted) through April and declining in May after the first state lockdown.



Safe Travels Hawaii

On October 15, 2020, a pre-travel NAAT testing option was implemented allowing arriving travelers to avoid Hawaii's mandatory 14-day quarantine. Travelers are required to test negative on a NAAT COVID-19 test, during a 72-hour period prior to boarding and arrival in Hawaii. Travelers must also register with the State of Hawaii's Safe Travels Hawaii system to report and manage their trip via the online form.

Just prior to October 15, an invitation was made to the author to conduct a "surveillance" of arrivals who would be re-tested for COVID-19 infection and evaluate the state's Safe Travels Hawaii program at the level of test performance and at the level of public health intervention.

A clear mandate was made that the investigation in all aspects would be conducted independently of public and/or private sector interference.

Equally important was the State's agreement to provide the resources and data from both the private sector and relevant public state institutions needed to initiate and complete the project starting on October 16 and continuing to the end of December 2020.

Previously, on June 9, 2020, Brown, La Croix, and Miler published via UHERO/East West Center/John A Burns School of Medicine a proposal, *Prevention of Travel-related Reintroduction of COVID-19 Infection in the State of Hawaii*². This publication was the impetus for this follow up surveillance study.

METHODS AND STUDY PLAN

The initial study plan and methods, with the same title (*Surveillance of COVID-19 infection in pre-tested travelers to Hawaii*: Confidential: F DeWolfe Miller: at the request of Lt. Gov. J. Green) was prepared as a guide for this study.

The implementation required changes in the original proposal. Modifications had to be made in the first week. Regardless, the same level of methodological rigor was maintained throughout the investigation.

On 10/19/20, surveillance on selected arriving travelers by an additional NAAT test for SARS-CoV-2, or an EUA approved antigen test, was implemented as a direct evaluation of prior travel screening and NAAT test sensitivity.

The provisional design was to re-test with a NAAT test or antigen test for SARS-CoV-2 on day ~ 4 after arrival or on arrival depending on arrival location and evaluations were made accordingly.

The participants were to be selected via the Safe Travels Hawaii, implemented by the State Office of Enterprise Technology Services (ETS) by a probability representative sample selection method. The target population was travelers to Hawaii on defined dates and was impossible to know beforehand, typically a requirement for prior estimation of sampling errors (Leslie Kish: *Survey Sampling*)², nor was there a sampling frame. The sample selection method was <u>systematic sampling</u>³, which can be readily adapted to select passengers from flights to Hawaii.

Sampling and Sample Size

The percentage of passengers sampled from each arriving plane was determined by the epidemiology statistics team to ensure sufficient statistical precision. For example, starting from a random number x between 1 and 10, each tenth passenger will be selected. For example, if x = 5, the 5^{th} passenger will be selected, the 15^{th} , 25^{th} passenger, and so on until a sufficient sample is selected from a given arrival. If there are 200 passengers, then 20 would be selected. For this example, every arrival would provide a 10% selection of passengers. A final sample of 1,000 persons will require systematic sample selection from 10,000 travelers.

Given that each passenger will have registered and provided data to the Mandatory State of Hawaii Travel and Health Form (https://travel.hawaii.gov/#/), which produces a unique QR code for each passenger, the selection process can be incorporated into this system, providing a systematic.selection at boarding time. This link assigns a surveillance ID for each person's test results, provides instructions for post-arrival testing locations, ties together demographic data such as age, gender, visitor (address), resident (address), contact information, instructions regarding test results, and other variables.

The State ETS office drew 10% samples using the Safe Travels platform for plane arrivals at the four State airport arrivals as described above. An invitation to participate in the project was sent to each selected passenger. The invitation is attached.

Laboratory Testing

Screening: departing passengers prior to NAAT testing are screened (self-screened) for COVID-19 symptoms and again checked for fever just prior to boarding.

Note that symptom screening will impact NAAT testing by increasing results sensitivity, multiplicatively (see attached Screening Multiplicative Probability).

Arriving passengers who were selected by the 10% systematic selection process were invited to get a free post arrival test in Hawaii. Where and when the specific post arrival test was located depended on the arrival airport.

Nasopharyngeal or other approved specimens were taken on arrival <u>or</u> 4 days after arrival by project laboratory partners. Rapid NAAT test for SARS-CoV-2 or antigen capture test on these specimens were completed and the results provided to the traveler, the project and public health authorities.

Instructions were also provided to travelers whose re-test was positive. Possible false positives were re-tested by NAAT.

Participating Trusted Testing Partners

Travelers, to participate, had to have a negative NAAT pre-boarding result from a US Mainland Trusted Testing Partners. These approved testing laboratories uploaded results to the <u>Safe</u> Travels Hawaii web site.

See attached document: Local Trusted Testing Partners in Hawaii

Data

The testing partners reported data in different formats. The project did not have, for every partner, control over how data was formatted and forwarded to the project. Nevertheless, strict secure data transfer, databasing, and storage were maintained throughout the project. An example of the ideal format is given below in spreadsheet format:

10/19/2020 xxxxxxxxxxxx 11/18/1942 M xxxxxxxx COVID- Negative 10/20/2020 xxxxx	Collection Date	Patient Name	DOB	Gend Gender	Accession	Test Name	Result	Result Date	Phone	Visitor Resident
	10/19/2020	xxxxxxxxxxxxx	11/18/194	12 M	XXXXXXXX	COVID- 19 Intern	Negative	10/20/2020	XXXXX	

Some testing partners provided data in spreadsheet format by total tested and total positive per day. Others, provided a simple table with summary test numbers and counts of test positives.

Analysis

Analysis was carried out at different levels of detail or data aggregation depending in part on how data were collected and reported.

Unit of observation:

- 1. Ecologic level are data aggregated by time and / or location.
- 2. Grouped data but with more specification at the individual level.
- 3. Joint individual and exposure level of observation.

Calculation of post arrival test positive estimates (i.e. pre-travel test negative) is trivial and given the sampling method, estimation of systematic sampling errors and confidence intervals is straightforward¹ and accomplished by software in hand (Epi Info 7.2.3.1).

In this investigation, COVID-19 cases acquired in institutional settings, for example incarceration or health care institutions, and including those for geriatric care, are not included in aggregate data. Transmission in these settings has not been related to travel.

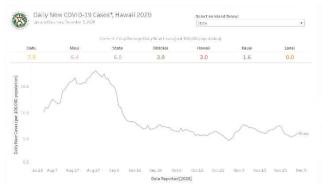
RESULTS

Analysis and results of the project were made at different levels of data aggregation and detail.

This analysis covers the entire period of the epidemic in Hawaii to end of date of the project. The first question is, what insight can the pattern of the epidemic in Hawaii from its beginning to 12/1 end of project show?

After the recognition that the COVID-19 pandemic had arrived in Hawaii in March and COVID-19 cases begin to increase, travel to Hawaii was canceled on March 28 by the State.

Following 7 weeks of single digit new case counts each day, by late June case numbers began to increase sharply (**Figure 2**, 7 day moving average: DOH Dashboard). The daily new case counts peaked in mid-August and then declined late September, after which case counts varied from \sim 50 to \sim 150 per day. From October 16 to December 1, there were 345,788 at of state arrivals.



There were 44 new cases in Hawaii on December 1, 2020, the last day of this investigation. Given the generally flat 7-day moving average over this period, compared to the August surge, any relative changes due to Safe Travels, would be speculation.

We next the address the question, was there a significant increase in cases in Hawaii over the period of the project during an arrival of

345,788 travelers after the implementation of preboarding testing? **Figure 3** below shows proportions of positive cases of those tested for COVID-19 over time as reported by DOH.

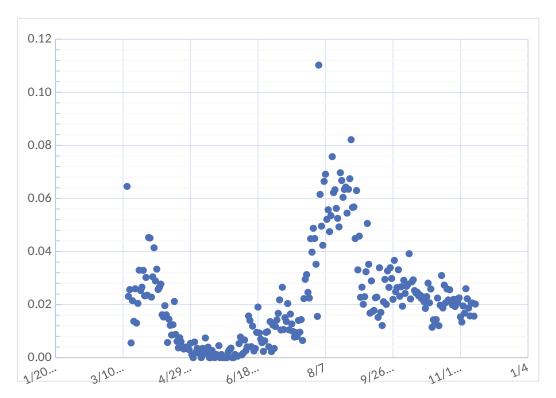


Figure 3. The red dot is October 15, 2020, project start. The last dot is Nov 26, 2020 near project end. Proportions of cases positive are lower than earlier in the year. Although there is variation over the project period, there is no clear trend. The pattern during the project period appears to be lower than in August.

Figure 4 is taken from **Figure 3** but includes only the period of October 15 to November 26, 2020. A regression line was fitted and shows a slightly negative slope (-5E-05x).

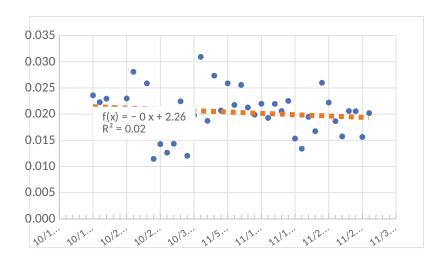
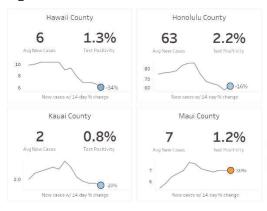


Figure 4 does not show evidence of an increase in the proportion of cases positive over the period of the project which the first phase of Safe Travels Hawaii.

Figure 5 shows ecologic data analysis provided by DOH Dashboard as of Dec 3. **Figure 5**.



New cases for all counties show flat to downward trends.

7-day rolling average of daily newly reported cases per 100,000 residents. Hawaii has the lowest in the nation at 6.

Analysis at the County level given in Table 1 shows an overall pragmatic and empirical result.

		Table 1		
		COVID1		
	Total	9 +		
	Arrival		Per	per
Island	S	Traveler	traveler	1000
			0.00055429	
Oahu	182,212	101	9	0.5543
Kauai	47,998	43	0.000896	0.8959
			0.00057969	
Maui	115,578	67	5	0.5797
Totals	345,788	226	0.00065358	0.6102

(Data for Hawaii island is shown separately.)

These data are the number of arrivals and number of travelers with COVID-19 positives numbers by county, excluding the Big Island, which was provided courtesy of the Hawaii State Department of Health (DOH) and had been collected for the project (October 15 to November 30). These were individuals who, during the project, pretested negative prior to boarding, were travelers to Hawaii and subsequently reported COVID-19 positive to DOH after arrival.

Similar to the time trend ecologic study above, these empirical results provide a level of analysis specific to preboard testing and post arrival COVID-19 test positivity. Note: not all 345,788 travelers were tested and tested negative prior to boarding. Approximately, 20% of arrivals were exempt travelers⁴. If these exempt travelers contributed to 226 positives, then the per capita base of 0.61/1,000 could be overestimated and lower (less than 0.61). If no contribution by exempt travelers to infection was made, then this estimate is underestimated, for example 0.61 to 0.76 / 1,000. Also, individuals who arrived, where infected and remained asymptomatic may have been missed.

Direct Retesting of Negative Pretested Arrivals

In this analysis, there were *n* participants tested by several contributing Trusted Testing Partners that reported aggregate data over time period. A total number of tests were completed and number positive reported in tables. Data at the individual level were not reported.

Big Island Hawaii Results

Direct retesting of negative pretested arrivals began at both arrival airports on the Big Island (Kona and Hilo) on October 15, 2020. All arriving passengers were retested at the airport with BD VeritorTM System rapid antigen capture tests. The sensitive of this assay is published in the product inserts: assuming a background prevalence of 1% or less, the NPV (negative predictive value) was 99.8%. A more accurate assessment of the BD sensitivity test requires the

multiplicative probably estimate given a NAAT negative pre-test given after preflight screening (a multiplicative probability analysis of BD system sensitivity is attached).

Note that systematic sampling was not done on arrivals at the Big Island airports. All arriving passengers were tested.

The following table shows an example of results for October (15 to 26).

Table 2 Hawai'i Island Covid Strike Team Report:

Hawai'i Island Covid Strike Team Report									
Location	Date	BD Rapid -	BD Rapid +	BD Total	Reflex PCRs	Positive PCR			
Hilo Airport	10/15/20	120	0	120	0	0			
Kona Airport	10/15/20	899	1	900	1	0			
Hilo Airport	10/16/20	57	0	57	0	0			
Kona Airport	10/16/20	736	3	739	4	0			
Hilo Airport	10/17/20	80	0	80	0	0			
Kona Airport	10/17/20	863	6	869	7	0			
Hilo Airport	10/18/20	34	0	34	0	0			
Kona Airport	10/18/20	601	1	602	2	0			
Hilo Airport	10/19/20	35	0	35	0	0			
Kona Airport	10/19/20	466	1	467	1	0			
Hilo Airport	10/20/20	41	0	41	0	0			
Kona Airport	10/20/20	408	2	410	3	1			
Hilo Airport	10/21/20	40	0	40	0	0			
Kona Airport	10/21/20	485	3	488	4	0			
Hilo Airport	10/22/20	62	0	62	0	0			
Kona Airport	10/22/20	643	5	648	7	1			
Hilo Airport	10/23/20	38	0	38	0	0			
Kona Airport	10/23/20	542	3	545	3	1			
Hilo Airport	10/24/20	40	1	41	1	0			
Kona Airport	10/24/20	576	1	577	1	0			
Hilo Airport	10/25/20	32	0	32	0	0			
Kona Airport	10/25/20	470	6	476	8	1			
Hilo Airport	10/26/20	36	0	36	0	0			
Kona Airport	10/26/20	327	6	333	8	5 pending			
Hilo Airport	10/27/20			0					
Kona Airport	10/27/20			0					
Hilo Airport	10/28/20			0					
Kona Airport	10/28/20			0					
Hilo Airport	10/29/20			0					
Kona Airport	10/29/20			0					
Hilo Airport	10/30/20			0					
Kona Airport	10/30/20			0					
Hilo Airport	10/31/20			0					
Kona Airport	10/31/20			0					
TOTAL FOR MONTH OF OCTOBER =		7631	39	7670	50	4			

Interpretation: In this first report, a total of 7,670 arriving passengers were tested between October 15 and October 26. Of these, 50 were positive by BD testing. The 50 BD positive tested passengers were recalled (BD test results were available in 30 minutes) and retested by Reflex PCR. Of the 50 BD positives, 4 were confirmed positive by Reflex PCR.

False positive proportion was high, 92% of positive tests. The overall true positive was 4/7670, equal to 0.52 positive post-test /1,000 pre-travel tests.

The following **Table 3** is a summary of the Big Island post testing arrival program for two months. Total testing, the number positive and the rates changed over the two months. The number of positives and the rate increased in November.

Table 3							
Month	Total tested	Positive	Rate				
October	10,478	9	0.0009				
November	8,978	23	0.0026				
Total	19,456	32	0.0016				

Other Island Aggregated Results

The next **Table 4** shows summary data sent from 6 post testing partners and include data from Oahu and Maui. These results are from persons who were invited and participated in the <u>Safe Travels Hawaii</u> program. These post travel tests were NAAT tests and were taken 4 days after arrival. The data were posted only as totals. Maui data could not be separated from the total. The rate, given 18 positives was 0.0072 which is higher than the Big Island results. There were significant variations in positives over the time and by different providers.

Table 4

	Tested	Positive	Rate
Tota l	2,507	18	0.00718

Other Island Unaggregated Results

We review joint individual and exposure level observations. These results were from individuals who were invited by the Safe Travels Hawaii systematic sampling program. These post travel tests were NAAT tests and were taken 4 days after arrival. Data from this provider were available only for Oahu and Kauai.

Table 5

					Rate
	Positive	Negative	Total	Rate	Percent
Oahu	6	645	651	0.009	0.9217
Kauai	3	519	522	0.006	0.5747
Total	9	1,164	1,173	0.008	0.7673

As shown in Table 5, there were 1,173 invited participants. The results were 9 positive of the total who participated. The rate percent positive for Oahu 0.92 is close to twice the rate positive for Kauai 0.57. The actual numbers of positives were small and not statistically significant (p > 0.05).

A preliminary analysis of these results by visitor or resident are show in the next **Table 6**.

Table 6

Travele	Positiv	Negativ		
r	e	e	Total	Rate
Residen				
t	5	132	137	3.788
Visitor	2	731	733	0.274
Total	7	863	870	0.811

The measure of association, relative risk, of being positive for Resident was 13.4 (95% CI 2.6 - 68.3, p < .0001). This suggests that returning residents were more likely than visitors to test positive after a pretravel negative test. This observation should be considered with caution.

It is especially important to note that the number of persons invited to participate was much larger (~10 times) than the number of persons who participated. This introduced sampling bias for which it is difficult if not impossible to adjust.

Summary of All Post Testing

During this project, the *Surveillance of COVID-19 infection in pre-tested travelers to Hawaii*, there were 21,963 post arrival COVID-19 tests completed.

Collectively, the data for this study are heterogeneous. The data include broad time trend, ecologic, aggregate, as well as individual data. The data on individuals were reported both on the aggregate and individual level from a systematic sample of arrivals which had an exceptionally low participation. This issue, and a full evaluation and interpretation of the findings, including an assessment of bias, follows.

DISCUSSION

Outside travel to Hawaii has been restricted dating from last March 28, 2020. On October 15, 2020, this travel restriction was modified. Travel to Hawaii from the US Mainland required a negative pre-travel NAAT test taken no more than 72 hours (3 days) before travel by a Trusted Testing Partner, as a alternative to a 14 day quarantine.

The first step in the analysis was at the level of on-going transmission in the whole state over the time of the entire epidemic in Hawaii, which showed a very large increase in transmission occurring in the late summer months and ending in September with a 7-day average plateauing at

10 to 15 cases/100,000. A more detailed examination of the epidemic curve, specificity during the 6-week project period, found remarkable daily variation but no significant increase beyond what would be explained by local community transmission and local clusters. A fitted linear regression line had an overall negative slope. This includes 3 complete lifecycles of the virus without a clearly marked undeniable spike.

The next level of analysis shown in **Table 1**, found an overall result of 0.65 positive tests per 1,000 visitors who enrolled in pretravel testing and gives an overall assessment of the pre-test <u>Safe Travels Hawaii</u> program, which is an important empirical result. From a public health perspective, this is a valid assessment of a public health intervention.: First there was restriction of travel and then removal of the restriction with an intervention to prevent introduction of additional COVID infection in the Islands. This level of evaluation is a pragmatic reality. In relation to measures of other public health interventions, for example regulation of air pollution levels and subsequent health effects, these results are far superior in regard to a direct causal relationship.

Given other island-based individual and community-based prevention measures, these results suggest a very remote probability of an unknown infected arrival, who is non-adherent and infects one or more residents. Decision makers should carefully and independently weight *that* probability in regard to local health care resources and economic impacts.

However, the above results in Table 1 do not provide detail on the numbers of positive persons by date over the period of the project. The numbers of positive travelers may have changed over this period (~ 6 weeks) perhaps reflecting large increases, decreases or other significant changes in COVID-19 transmission that cannot be shown from these data.

Figures 1 through 5 show patterns of transmission during the period of the project. None showed or reflected any trend (possibly a small downward trend), especially, relative to the major surge peak that preceded the project in late summer and early fall months.

Ironically, during the week of October 20, 2020, a COVID-19 infected exempt worker traveled inter island from Oahu to Lanai and triggered a super spreader event. Previously, the small island of Lanai had been free of infection. Had the exempted worker been tested prior to inter island travel, the outcome would have been different.

Post arrival retesting on the Big Island retested all nonexempt arrivals. There was no sampling and therefore no sampling or sampling error estimates.

The sensitivity of this test in the context of multiple screens should be elevated based on the sensitivities of the prescreen and pre-tests and how these effect post arrival testing sensitives. For example, given a combined multiplicative probability on the prescreen and the NAAT pretravel testing estimated at 0.9935, the estimated sensitivity of the BD VeritorTM System would be ~.9991 (estimation included in Attachment). Moreover, there was essentially a 72-hour or a 3-day period plus a flight to Hawaii time period between the two tests.

On the Big Island, numbers tested, the number positive, and the rate of positives changed from October to November. The number positive and the rate of positives increased. These are the

only data from the project that can be associated with a change over time. There was no known change in pre-travel NAAT testing methods nor was there a change in arrival testing methods on the Big Island. Information on COVID-19 infection rates from departure locations on the Mainland for travelers who participated in the Big Island study were not included in the data provided. Background COVID-19 rates have a direct linear relationship on test/retest results as described in the June UHERO publication². COVID-19 rates were increasing on the Mainland west coast in November.

The Big Island outcome on test/re-test has strong quantitative validity and was not based on a sample. Moreover, the project was unable to identify a local Big Island resident who had been secondarily infected by a pre-tested arrival. Although this cannot be ruled out. Had the project been continued to the original end date, December 31, it may have been possible to evaluate this infection likelihood with additional data. The result from 19,456 tests on the Big Island was an overall 0.0016. Note that false positive rates were high.

In parallel, on the other islands, an evaluation based on a 10% systematic sample of arrivals included results from 2,507 individuals by the end of November. There were18 individuals who tested negative prior to boarding and tested positive by NAAT test 4 days later for a rate of 0.00718. We owe all these participants a very large debt of gratitude. There were many difficulties that these individuals had to overcame to get the post arrival test. Many others tried and failed. The author, whose name was also included on the invitation, was contacted by many of these frustrated visitors and returning residents. Why promised free tests were not readily available was difficult to explain to good faith intended participants. Moreover, some participants were quarantined despite having a negative pre-travel test.

The results, 0.00718 are higher compared to all other estimates, especially compared to the results from the Big Island, i.e. 0.0016. Given that 10% of travelers were, ostensibly, invited and 2,507 participated, there was a very low participation rate. This is known in epidemiology as nonresponse and in this study a large potential for selection bias or in this case, sampling bias. This must be considered in the interpretation of these results. Consideration of the impact on sampling bias must be made. One approach (there are no "good" approaches to address this without more information), is to imagine the result if there had been full participation of \sim 30,000 persons. In the opinion of this epidemiologist, the estimate would have been lower.

Epidemiological experience suggests that travelers who had a nagging suspicion that they have had a probable exposure would more likely make the effort, significant given the circumstances, to get retested. Sampling inferences that would ordinarily be made from a systematic sample cannot be made. The interpretation is limited to "some arrivals who tested negative prior to travel, tested positive on arrival after 4 days". Numeral estimates are not valid.

Conclusions

The data on test/re-test at different levels of evaluation has been collected, evaluated, and presented. In absence of continued surveillance that may be able to address some of the

limitations of this study, the data presented are useful as empirically valid. The data available have been presented objectively.

The readers and those who make policy are provided with valuable information on which to make difficult decisions given the absence of other relevant local information.

Analysis of data showed positivity associated with Oahu compared to Kauai and returning resident compared with visitor. Conclusions from these two observations must be very tentative without additional data.

Recommendations

It is suggested that when making costly decisions with both epidemiologic and economic tradeoffs, there are several important prevention measures that should be made regardless.

- 1. Significantly improve **visitor education** regarding behavior-related transmission prevention while in Hawaii, which include a number of prevention related items.
- 2. Urge returning **residents**, who will potentially be joining family members, should take additional precautions until they can be certain about their own infection status. For example, re-testing, mask at all times, and related precautions. Project results are consistent with this recommendation.
- 3. Review and tighten travel **exemptions.** These exemptions have contributed to community transmission may have created undetectable bias in this analysis. This is a serious oversight that undermines the validity of the pre-travel testing project.
- 4. Implement a more detailed and **expanded pre-screen** prior to the first preflight NAAT test. This is a hugely under recognized issue that could impact testing sensitivity exponentially.
- 5. Develop a **local app** for exposure and contact tracing.
- 6. Follow-up **BD Veritor System** positive test results with a NAAT.
- 7. The **BD Veritor System** for Rapid Detection of SARS-CoV-2 or related assays are an excellent and inexpensive substitute. However, in a low prevalence background, the false positive rate will be high (as seen in the Big Island data). All BD positive tests should be followed with a NAAT.
- 8. Recommendation for a **second post arrival** test may be justified and more efficient if consideration is given to a more defined group of arrivals, specifically **returning residents**. A rapid antigen capture test <u>on arrival</u> would be cost efficient and implementable.

Budget

For the period of 10/19/20 -12/31/20, 2020, it is estimated that Hawaii will receive 200,000 – 300,000 travelers (tourists and returning residents). The percentage of passengers that need to be tested for the surveillance program should not exceed 10 percent according to statistics experts who will be administering the study with the expectation of needing between 20,000 and 30,000 tests. The budget number shall reflect the costs of these tests.

Acknowledgements

Dr. L. Thomas Ramsey, Emeritus Professor of Mathematics, UH; Dr. Sumner La Croix, Emeritus Professor of Economics, UH; Dr. Chad Meyer, M.D., Infectious Diseases.

References

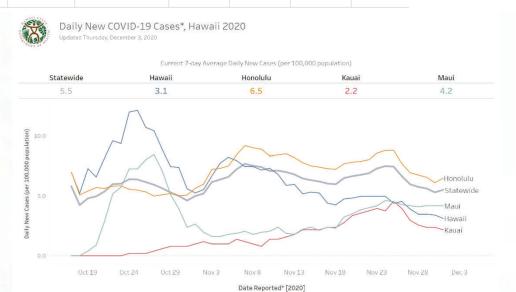
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Attachments

Screening Multiplicative Probability

Assuming that symptom pre-test screening (i.e. fever, cough, etc.) has a low sensitivity for COVID-19, essentially due to asymptomatic infection with a probably or P = .35 and the second NAAT test has a sensitivity of P = .99.

	NAAT Sensitive e	9		
	Pre=Screening Se	nsitivity .35		
PreScreen	1-p =	0.65	p =	0.35
NAAT	1-p =	0.01	p =	0.99
	(1-p) X (1-p)=	0.0065		
	1-[(1-p)X(1-P)]=	0.9935		
NAAT	1-p =	0.0065	p =	0.9935
BD	1-p =	0.14	p =	0.86
	(1-p) X (1-p)=	0.00091		
	1-[1-p)X(1-P)]=	0.99909		



Frequency of Mask Wearing ... Kauai lowest at 79%

7 day moving daily average cases per 100,000 population, Dec 1

Table 1 Summary of the Performance of the BD Veritor System for Rapid Detection of SARS-CoV-2 Compared to RT-PCR for Nasal Swabs

	Reference PCR Results				
BD Veritor Results	POS	NEG	Total		
POS	26	0	26		
NEG	5	195	200		
Total	31	195	226		

PPA: 84% (C.I. 67%-93%) NPA: 100% (C.I. 98%-100%) PPV: 100% (C.I. 89%, 100%)

OPA: 98% (C.I. 95%-99%)

NPV: 97.5% (C.I. 95%, 99%)

EXPLANATION OF TERMS:

C.I.: Confidence Interval

PPA: Positive Percent Agreement = True Positives / True Positives + False Negatives

NPA: Negative Percent Agreement = True Negatives / True Negatives + False Positives.

OPA: Overall Percent Agreement = True Positives + True Negatives / Total Samples PPV: Positive Predictive Value = True Positives / True Positive + False Positive

NPV: Negative Predictive Value = True Negatives / True Negative + False Negative

Table 2 Hypothetical Positive and Negative Predictive Values for the BD Veritor System for Rapid Detection of SARS-CoV-2 compared to PCR

			PPV		NPV	
Prevalence	Sensitivity	Specificity	Estimate	95% C.I.	Estimate	95% CI
1.0%	84.0% (26/31)	100.0% (195/195)	100.0%	(33.2%,100.0%)	99.8%	(99.7%, 99.9%)
2.0%			100.0%	(50.1%,100.0%)	99.7%	(99.3%, 99.9%)
5.0%			100.0%	(72.1%,100.0%)	99.2%	(98.3%, 99.7%)
10.0%			100.0%	(84.5%,100.0%)	98.2%	(96.4%, 99.4%)
13.7%			100.0%	(88.6%,100.0%)	97.5%	(94.9%, 99.1%)
15.0%			100.0%	(89.7%,100.0%)	97.2%	(94.4%, 99.0%)
20.0%			100.0%	(92.5%,100.0%)	96.1%	(92.2%, 98.7%)
25.0%			100.0%	(94.2%,100.0%)	94.9%	(89.9%, 98.2%)

EXPLANATION OF TERMS:

C.I.: Confidence Interval

PPV: Positive Predictive Value = True Positives / True Positive + False Positive NPV: Negative Predictive Value = True Negatives / True Negative + False Negative

Collaborating Laboratories (Trusted Testing Partners)

Island Testing Locations Address

Premier Medical Group
Call number listed to make an appointment and be directed to location
Hilo
808-452-8434
Kona
808-452-8374

Premier Medical Group
Daily 9am-12 Noon @ Ko Olina Center
(fronting Just Tacos Mexican Grill & Cantina) 92-1047 Olani Street
Kapolei, HI 96707
808-387-3732

Adventist Health Castle Monday-Friday 10am-2pm 640 Ulukahiki St Kailua, HI 96734 808-263-5142

Sheraton Princess Ka'iulani Hotel – Doctors of Waikiki Daily 9am-Midnight 120 Ka'iulani Ave, Suite KW10&11 Honolulu, HI 96815 808-922-2112

Sheraton Waikiki – Hawaii Pacific Health Clinic Straub Doctors on Call Daily 10am-8pm
Appointment required: https://www.clinicallabs.com/covid/
2255 Kalakaua Ave.
Manor Wing, Shop 1
Honolulu, HI 96815
808-971-6000

Kaiser Permanente of Oahu Resident Kaiser Permanente Members must call the appointment Testing site: 1052 Ahua St. Honolulu, HI 96819

Straub Medical Center – Kahala Clinic & Urgent Care Daily 1pm-6pm Appointment required: https://www.clinicallabs.com/covid/ 4210 Waialae Avenue, Suite 501 Honolulu, HI 96816 808-462-5300 Straub Medical Center – Kapolei Clinic & Urgent Care Daily 1pm-6pm Appointment required: https://www.clinicallabs.com/covid/ 91-5431 Kapolei Parkway, Suite 1706 Kapolei, HI 96707 808-426-9300

Ward Village Clinic & Urgent Care
Daily 1pm-6pm
Appointment required: https://www.clinicallabs.com/covid/
1001 Queen Street, Suite 102
Honolulu, HI, 96814
808-462-5200

Urgent Care 808.263.CARE (2273)

Go to www.ucarehi.com to schedule an appointment. Select location, day and time that you would like to come in for your test.

Register online and complete the consent forms when scheduling the appointment. Results are completed in 48-36 hours. Consumers register on DLS portal for access to results. https://dls.atlaspatientportal.com/#/

Kailua Location 660 Kailua Rd Kailua, HI 96734 Monday – Friday: 8 am – 7 pm Saturday & Sunday: 9 am – 5 pm

Kapolei Location 890 Kamokila Blvd Kapolei, HI 96707 Monday – Friday: 7 am – 7 pm Saturday & Sunday: 8 am – 6 pm

Pearl City Location 1245 Kuala Street, Suite 103 Pearl City, HI 96782 Monday – Friday: 7 am – 7 pm Saturday & Sunday: 8 am – 6 pm

Waikiki Location 1860 Ala Moana Blvd #101 Honolulu, HI 96815 Monday – Friday: 9 am – 3 pm Saturday & Sunday: Closed

Kauai Princeville Airport - Premier Medical Group

Outside of terminal (north end of the airport) Daily 11am-3pm 5-3541 Kuhio Hwy Kilauea, HI 96754 808-387-3732

Wilcox Medical Center - Hawaii Pacific Health Monday-Saturday 8am-1pm 3-3420 Kuhio Highway Lihue, HI 96766 808-245-1100

Kaiser Permanente of Kauai 4366 Kukui Grove St Ste 101, Lihue HI, 96766

Kaua'i Urgent Care Daily 10am-7pm 4484 Pahee St. Lihue, HI 96766 808-245-1532 Hawaii

Kaiser Permanente of Hawaii Island 1292 Waianuenue Ave. Hilo, HI 96720

Kona Medical Office 74-517 Honokohau Street Kailua-Kona, HI 96740



Aloha recent traveler to Hawai'i,

Thank you, for your participation in the <u>Safe Travels Hawaii</u> pre-arrival testing program. You have been randomly selected to take a second COVID-19 test. The test is free, entirely voluntary, and can be taken at many convenient locations on island.

We are working hard to help keep Hawai'i a safe place both for our residents and visitors and we appreciate your joining us in this effort. Your participation is a significant contribution to the health and well-being of the people of Hawaii and our guests. We highly encourage and greatly appreciate your support through participation in this follow-up testing.

We are offering this second test to carefully assess our overall pre-travel testing program. We want to keep Hawaii safe during this pandemic.

If at all possible, tomorrow please walk in to one of the convenient testing locations listed below. Show this notice to the clinician upon arrival and they will provide you with your free test.

We hope that your time in the islands will be safe, healthy and rewarding. Please help us to keep Hawaii a safe travel destination by wearing a mask, practicing physical distancing, washing your hands frequently and avoiding large gatherings or crowded spaces. If you develop symptoms consistent with COVID-19, please self-isolate immediately and seek further medical evaluation as necessary.

Submitting this notice to the clinician at your selected testing location and providing your sample constitutes consent to be part of <u>Safe Travels Hawaii</u> COVID-19 Follow-Up Testing Program.

Mahalo,

F. DeWolfe Miller, MPH, PhD Project Lead, Safe Travels Testing Evaluation Program

Joshua Green Lieutenant Governor of Hawaii