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From: Chief, Bureau of Medicine and Surgery
To: Deputy Chief of Naval Operations, Manpower, Personnel, Training, and Education (N1)

Subj: DISEASES TARGETED WITH MANDATORY VACCINATIONS FOR UNITED STATES NAVY ACTIVE DUTY AND RESERVE PERSONNEL

1. Subject matter experts at the Bureau of Medicine and Surgery have compiled the below facts on certain mandatory vaccines for United States (U.S.) Navy Active Duty and Reserve personnel. The information below provides some of the scientific and medical rationale for the vaccine requirements for vaccine-preventable diseases that would otherwise create risk to the readiness of the Force.

2. Coronavirus Disease 2019 (COVID-19)

a. Means of infection and infectivity. Person-to-person transmission via respiratory fluids, composed mainly of respiratory droplets and aerosol particles. Basic reproduction numbers (i.e., the number of people who become ill due to exposure to a single case) are estimated to be 2.8 for the original strain, 4-5 for the Alpha variant, and 5-8 for the Delta variant. In other words, every case of Delta variant COVID-19 can infect 5-8 people if effective countermeasures are not employed.

b. Disease's specific harm to health. COVID-19 symptoms are extremely unpredictable, and range from non-existent (asymptomatic) to death. The most common symptoms are: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, loss of taste or smell, sore throat, congestion, nausea or vomiting, and diarrhea. These more minor symptoms result in clinic visits, time off work, reduced productivity, possible temporary incapacitation (requiring bed rest). Most serious cases may require hospitalization, the need for oxygen support, and mechanical ventilation. Between 17 December 2020 and 31 August 2021, six Sailors and one Marine have died due to COVID-19; none of them were fully immunized.

(1) The risk of complications from COVID-19 illness is significant. A recent Center for Disease Control and Prevention (CDC) report showed COVID-19 patients had nearly 16 times the risk for myocarditis compared with patients who did not have COVID-19, and this risk was higher in younger age groups.

(2) In addition, there is a significant risk of persistent COVID symptoms after recovery from acute illness, or "long COVID." A recent study found that in patients who had recovered from COVID-19, 87.4% reported persistence of at least one symptom, particularly fatigue and

dyspnea at an average of 60 days after symptoms onset. Another found that nearly 2/3 of people hospitalized with COVID-19 still had symptoms 6 months later.

c. Treatment required and level of medical treatment facility capable of delivering that treatment. While mild cases may only require isolation and routine symptomatic care, severe cases may rapidly require intensive resources (Role 3 hospital with Intensive Care Unit (ICU) level care and mechanical ventilation) that are not routinely available in a deployed setting. A recent study of over 43,000 COVID-positive patients in England showed the rate of hospitalization within 14 days of testing was 2.2% for the Alpha variant and 2.3% for the Delta variant (74% were unvaccinated).

d. Efficacy/effectiveness of available vaccine(s). In large phase III trials, the Food and Drug Administration (FDA) approved COVID-19 vaccine was shown to have over 94% efficacy at preventing symptomatic COVID-19. For the same vaccine, against the Delta variant in a real world setting, studies show 88% effectiveness against symptomatic disease, to include hospitalization and death. Nationally in the United States, per the CDC, from January through August 2021, the unvaccinated comprised over 99% of all hospitalized COVID patients (over 1.6 million) as well as over 99% of all COVID-19 deaths (over 264,000). There have been zero COVID-19 deaths of Sailors or Marines among those fully immunized, and zero deaths of Sailors or Marines due to vaccination administration.

e. Likelihood of infection if unvaccinated. In a recent (24 Aug 2021) CDC report of over 43,000 SARS-CoV-2 infections in Los Angeles County, California (population approx. 9.6M), over 71% of the infections were unvaccinated and over 85% of hospitalizations were unvaccinated. The same study reported infection and hospitalization rates among unvaccinated persons were 4.9 times and 29.2 times the rates of those for fully vaccinated people, respectively. According to current surveillance data, nearly 87% of hospitalized Department of the Navy (DON) Active Duty COVID-19 cases since 17 December 2020 are among unvaccinated service members. For DON Service members who had COVID-19 since December 2020, surveillance data indicates that hospitalization rates are approximately 500 per 100,000 cases, which is substantially higher than for influenza (see paragraph 2b).

f. Other methods of prevention. For diseases transmitted by respiratory droplets and aerosol particles such as COVID-19, the CDC recommends non-pharmaceutical interventions (NPI) in addition to vaccination. NPIs recommended by the CDC to avoid contracting or spreading COVID-19 have been categorized as either personal or community based. Personal interventions comprise respiratory hygiene (covering the mouth and nose during coughing and sneezing), avoiding touching the face, frequent hand washing, cleaning and disinfecting objects and surfaces that are frequently touched, avoiding sick people, and self-quarantine when a person feels unwell. Community-based actions include public education through a variety of communication strategies, social distancing (6 feet), wearing facemasks, ensuring adequate ventilation of indoor spaces, and restrictions on public gatherings.

g. Efficacy of non-pharmaceutical interventions. Despite the ability of NPIs to prevent respiratory virus transmission, there are very limited data available on their effectiveness at the individual level. Data on the effectiveness of NPIs implemented as community-wide mandates

(where NPI impacts both source control and personal protection) would not be applicable at the individual level.

(1) Recent studies have shown efficacy of mask wearing to prevent COVID-19. During a COVID-19 outbreak on the *USS THEODORE ROOSEVELT*, persons who wore masks experienced a 70% lower risk of testing positive for SARS-CoV-2 infection. Similar reductions have been reported in case contact investigations when contacts were masked and in household clusters in which household members were masked.

(2) However, in order to be effective, NPI must be implemented rigorously and continuously, and breaches in implementation are common. This is particularly true in communal environments such as aboard ships, in barracks, or in field situations; high rates of transmission have been documented in schools and household settings. One study during a recent mask mandate found that 90% of 5,893 individuals were observed not wearing a mask or not wearing it correctly, despite 75.9% of those individuals self-reporting always wearing a mask in public.

(3) Similarly, NPI such as masks provide measures of community protection, as described above, only while they are in use. Because the scientific and medical communities predict that SARS-CoV-2 will remain in global circulation as an endemic virus, the risk to the Force associated with COVID-19 in unvaccinated personnel may exist in perpetuity.

h. Scientific and Medical opinion on whether non-pharmaceutical interventions, alone or in concert, will be successful in meeting the compelling government interest. Any combination of NPI, in the absence of vaccination, are not likely to be effective at preventing COVID-19 outbreaks and their resulting impacts on the Navy's mission, especially in the setting of the highly contagious Delta variant. Unlike NPI, vaccination provides its full measure of protection in an enduring capacity, subject to potential boosters as recommended by the FDA. Vaccination is not subject to reductions in efficacy due to incomplete implementation as with NPI. For this reason, vaccination is significantly superior to NPI, and mask wearing, for preventing respiratory infections such as COVID-19, especially when only implemented at the individual level and not by the entire community.

3. Influenza

a. Means of infection. Person-to-person transmission via respiratory droplets. Basic reproduction numbers are estimated to be 0.9-2.1, which means, on average, a person infected with influenza will spread the virus to 1-2 other people, if no additional protective measures are in place.

b. Disease's specific harm to health. Typical symptoms include: fever, cough, sore throat, runny nose, muscle aches, headaches, fatigue, and vomiting / diarrhea (more common in children than adults). This results in clinic visits, time off work, reduced productivity, possible temporary incapacitation (requiring bed rest), and viral shedding, potentially infecting those who come in contact with the person. Hospitalization is rare among young adults with influenza, 3-7 per 100,000 age 18-49. The most common complications of influenza include secondary bacterial

pneumonia, exacerbations of underlying respiratory conditions, otitis media, laryngotracheobronchitis, and bronchitis. Other complications may include primary pneumonia, encephalitis, aseptic meningitis, transverse myelitis, myocarditis, pericarditis, and Guillain-Barré syndrome.

c. Treatment required and level of medical treatment facility capable of delivering that treatment. For mild cases, rest at home /in quarters (in isolation), oral rehydration, antipyretics, and medications to target symptoms. For severe cases or those with complications, hospitalization (role 3 hospital, minimum) and ICU-level care with mechanical ventilation may be required.

d. Efficacy of available vaccine(s). Although influenza vaccine effectiveness is variable from season to season, since 2003, on average it has been 40% (range 10-60%). In addition, influenza vaccination has been shown in several studies to reduce severity of illness in people who get vaccinated but still get influenza illness. Influenza vaccination can also reduce transmission of the virus, thus protecting family members, co-workers, and other contacts from getting sick. Some of these contacts may be more vulnerable to serious influenza illness, like babies and young children, the elderly, and those with certain chronic health conditions.

e. Periodicity of vaccine boosters. Annual vaccination is required due to changes in the circulating viruses.

f. Likelihood of infection if unvaccinated. If unvaccinated for influenza, a Sailor will have a higher risk of contracting the disease and transmitting it to co-workers. According to the Centers for Disease Control and Prevention, the estimated annual incidence of influenza infection is approximately 8% (varying from 3% to 11%); approximately half of these cases would be symptomatic. However, outbreaks can be explosive, with attack rates exceeding 60% over periods as short as 10 days.

g. Other methods of prevention. For diseases transmitted by respiratory droplets such as influenza, the CDC recommends NPI in addition to vaccination. NPIs recommended by the CDC to avoid contracting or spreading respiratory infections have been categorized as either personal or community based. Personal interventions comprise respiratory hygiene (covering the mouth and nose during coughing and sneezing), avoiding touching the face, frequent hand washing, cleaning and disinfecting objects and surfaces that are frequently touched, avoiding sick people, and self-quarantine when a person feels unwell. Community-based actions include public education through a variety of communication strategies, social distancing (6 feet), ensuring adequate ventilation of indoor spaces, and restrictions on public gatherings. The use of masks may be appropriate in certain situations such as during periods of high community transmission and when an individual or contact is immunocompromised.

h. Efficacy of other methods of prevention. Despite the potential for NPIs to prevent respiratory virus transmission, there are very limited data available on their effectiveness at the individual level. Data on the effectiveness of NPIs implemented as community-wide mandates (where NPI impacts both source control and personal protection) would not be applicable at the individual level.

(1) One published observational study out of Japan regarding influenza transmission showed the overall effectiveness of mask wearing was 8.6%, while handwashing showed a negative association (i.e., not protective). A meta-analysis of NPIs to prevent 2009 pandemic influenza infection showed a statistically significant protective effect for regular hand hygiene (38%) and a statistically non-significant protective effect for facemask use.

(2) In order to be effective, NPI must be implemented rigorously and continuously, and breaches in implementation are common. This is particularly true in communal environments such as aboard ships, in barracks, or in field situations; high rates of transmission have been documented in schools and household settings. One study during a recent mask mandate found that 90% of 5,893 individuals were observed not wearing a mask or not wearing it correctly, despite 75.9% of those individuals self-reporting always wearing a mask in public.

i. Medical opinion on whether other methods of prevention, alone or in concert, will be successful in meeting the compelling government interest. Any combination of NPI in the absence of vaccination are not likely to be effective at preventing influenza outbreaks and their resulting impact on the Navy's mission. Vaccination is not subject to reductions in efficacy due to incomplete implementation as with NPI. For this reason, and given the limited data available, it appears vaccination is significantly superior to NPI and mask wearing in particular, for preventing respiratory infections such as influenza, especially when only implemented at the individual level and not by the entire community.

4. Tetanus

a. Means of infection. The bacteria that causes tetanus, *C. tetani*, usually enters the body through a wound. In the presence of anaerobic conditions, the spores germinate. Toxins are produced and disseminated via blood and lymphatics.

b. Disease's specific harm to health. On the basis of clinical findings, three different forms of tetanus have been described.

(1) The most common type (more than 80% of reported cases) is generalized tetanus. The disease usually presents with a descending pattern. The first sign is trismus, or lockjaw, followed by stiffness of the neck, difficulty in swallowing, and rigidity of abdominal muscles. Other symptoms include elevated temperature, sweating, elevated blood pressure, and episodic rapid heart rate. Spasms may occur frequently and last for several minutes. Spasms continue for 3 to 4 weeks. Complete recovery may take months.

(2) Localized tetanus is an uncommon form of the disease in which patients have persistent contraction of muscles in the same anatomic area as the injury. These contractions may persist for many weeks before gradually subsiding. Localized tetanus may precede the onset of generalized tetanus, but is generally milder.

(3) Cephalic tetanus is a rare form of the disease, occasionally occurring with otitis media in which clostridium tetani is present in the flora of the middle ear or following injuries to the head. There is involvement of the cranial nerves, especially in the facial area.

(4) Complications of tetanus are common. Laryngospasm or spasm of the muscles of respiration leads to interference with breathing. Fractures of the spine or long bones may result from sustained contractions and convulsions. Hyperactivity of the autonomic nervous system may lead to hypertension or an abnormal heart rhythm. Nosocomial infections are common because of prolonged hospitalization. Secondary infections may include sepsis from indwelling catheters, hospital-acquired pneumonias, and decubitus ulcers. Pulmonary embolism is particularly a problem in persons who use drugs and elderly patients. Aspiration pneumonia is a common late complication of tetanus, found in 50% to 70% of autopsied cases. In recent years, tetanus has been fatal in approximately 11% of reported cases.

c. Treatment required and level of medical treatment facility capable of delivering that treatment. Tetanus cases must be treated in a tertiary care facility with capability to provide long term ICU care and mechanical ventilation. Tetanus immune globulin (TIG) is recommended for persons with tetanus. Intravenous immune globulin (IVIG) contains tetanus antitoxin and may be used if TIG is not available. Because of the extreme potency of the toxin, tetanus disease does not result in tetanus immunity. Active immunization with tetanus toxoid should begin or continue as soon as the person's condition has stabilized.

d. Efficacy of available vaccine(s). Efficacy of the tetanus toxoid has never been studied in a vaccine trial. It can be inferred from protective antitoxin levels that a complete tetanus toxoid series has an efficacy of almost 100%. In the series of 233 cases from 2001–2008, only 7 cases (3%) had received a complete tetanus toxoid series with the last dose within the last 10 years.

e. Periodicity of vaccine boosters. Every 10 years.

f. Likelihood of infection if unvaccinated. While tetanus is rare in the US (averaging 31 cases per year for 2000-2007), nearly all of those cases were in unvaccinated or under-vaccinated individuals. Tetanus is much more common outside the US; in 2015 there were approximately 209,000 infections and about 59,000 deaths globally. As noted above, vaccine efficacy is high, with over 32 times the risk for unvaccinated persons compared to vaccinated.

g. Other methods of prevention. Usual safety measures can help prevent injuries resulting in cuts or puncture wounds from contaminated objects.

h. Efficacy of non-pharmaceutical interventions. At the individual level, such accidents are common and have proven difficult to prevent.

i. Medical opinion on whether other methods of prevention, alone or in concert, will be successful in meeting the compelling government interest. Safety measures alone will not likely be successful in preventing tetanus-prone wounds.

5. Diphtheria

a. Means of infection. Transmission of diphtheria is most often person-to-person through respiratory droplets. Transmission may also occur from exposure to infected skin lesions or articles soiled with discharges from these lesions. The basic reproduction number is about 2.6.

b. Disease's specific harm to health. This may be a spectrum, but should include worst case scenarios and likelihood of worst case scenarios. Understand that co-morbidities play a significant role in these calculations, and our population tends to lack co-morbidities. The most common form of diphtheria results in a membranous pharyngitis and tonsillitis, with symptoms of fever, sore throat, malaise, and anorexia. While some patients may recover at this point without treatment, others may develop severe disease. The patient may appear quite toxic, but the fever is usually not high. Patients with severe disease may develop marked edema of the submandibular areas and the anterior neck along with lymphadenopathy, giving a characteristic "bull neck" appearance. If enough toxin is absorbed, the patient can develop severe prostration, pallor, rapid pulse, stupor, and coma. Death can occur within 6 to 10 days. Death occurs in 5-10% of diphtheria cases.

c. Treatment required and level of medical treatment facility capable of delivering that treatment. In addition to supportive care, as described for influenza and COVID-19, specific treatments include antitoxin and antibiotics. Diphtheria antitoxin, produced in horses, has been used for treatment of respiratory diphtheria in the United States since the 1890s. Diphtheria antitoxin is available only from CDC, through an Investigational New Drug (IND) protocol. Diphtheria antitoxin does not neutralize toxin that is already fixed to tissues, but it will neutralize circulating toxin and prevent progression of disease.

(1) After a provisional clinical diagnosis of respiratory diphtheria is made, appropriate specimens should be obtained for culture and the patient placed in isolation. Persons with suspected diphtheria should be promptly given diphtheria antitoxin and antibiotics in adequate dosage, without waiting for laboratory confirmation. Respiratory support and airway maintenance should also be provided as needed. Consultation on the use of and access to diphtheria antitoxin is available through the duty officer at CDC's Emergency Operations Center at 770-488-7100.

(2) In addition to diphtheria antitoxin, patients with respiratory diphtheria should also be treated with antibiotics. The disease is usually no longer contagious 48 hours after antibiotics have been given. Elimination of the organism should be documented by two consecutive negative cultures taken 24 hours apart, with the first specimen collected 24 hours after therapy is completed.

d. Efficacy of available vaccine(s). Diphtheria toxoid-containing vaccine has been estimated to have an efficacy of 97%.

e. Periodicity of vaccine boosters. Every 10 years in adults.

f. Likelihood of infection if unvaccinated. Diphtheria is rare in the U.S. (14 cases were reported between 1996 and 2018), but it is much more common outside the U.S. where vaccination coverage is suboptimal (4,500 cases worldwide in 2015).

g. Other methods of prevention. For diseases transmitted by respiratory droplets such as diphtheria, the CDC recommends non-pharmaceutical interventions (NPI) in addition to vaccination, although widespread vaccination has all but eliminated disease incidence in the U.S. (ex. no cases in 2017 and 2018 according to World Health Organization, which largely eliminated the subsequent need for diphtheria-related NPI in practice). NPIs recommended by the CDC to avoid contracting or spreading respiratory infections have been categorized as either personal or community based. Personal interventions comprise respiratory hygiene (covering the mouth and nose during coughing and sneezing), avoiding touching the face, frequent hand washing, cleaning and disinfecting objects and surfaces that are frequently touched, avoiding sick people, and self-quarantine when a person feels unwell. Community-based actions include public education through a variety of communication strategies, social distancing (6 feet), ensuring adequate ventilation of indoor spaces, and restrictions on public gatherings. The use of masks may be appropriate in certain situations such as during periods of high community transmission and when an individual or contact is immunocompromised.

h. Efficacy of non-pharmaceutical interventions. While we are not aware of any studies evaluating the efficacy of NPI specifically for diphtheria, it is likely the effectiveness of most NPI would be similar to that for other infections transmitted by respiratory droplets.

(1) Despite the potential for NPIs to prevent respiratory disease transmission, there are very limited data available on their effectiveness at the individual level. Data on the effectiveness of NPIs implemented as community-wide mandates (where NPI impacts both source control and personal protection) would not be applicable at the individual level.

(2) In order to be effective, NPI must be implemented rigorously and continuously, and breaches in implementation are common. This particularly true in communal environments such as aboard ships, in barracks, or in field situations; high rates of transmission have been documented in schools and household settings. One study during a recent mask mandate found that 90% of 5,893 individuals were observed not wearing a mask or not wearing it correctly, despite 75.9% of those individuals self-reporting always wearing a mask in public.

i. Medical opinion on whether non-pharmaceutical interventions, alone or in concert, will be successful in meeting the compelling government interest. Any combination of NPI in the absence of vaccination are not likely to be effective at preventing diphtheria outbreaks and their resulting impact on the Navy's mission. Vaccination is not subject to reductions in efficacy due to incomplete implementation as with NPI. For this reason, and given the limited data available, it appears vaccination is significantly superior to NPI and mask wearing in particular, for preventing respiratory infections such as diphtheria, especially when only implemented at the individual level and not by the entire community.

6. Pertussis. Note: there is no pertussis vaccine preparation that does not contain tetanus and diphtheria toxoids.

a. Means of infection. Transmission most commonly occurs person-to-person through contact with respiratory droplets, or by contact with airborne droplets of respiratory secretions. Transmission occurs less frequently by contact with an infected person's freshly contaminated articles. The basic reproduction number is about 5.5.

b. Disease's specific harm to health. The clinical course of pertussis is divided into three stages: catarrhal (with symptoms similar to the common cold lasting 1-2 weeks), paroxysmal (with more severe cough and paroxysms of numerous rapid coughs lasting 1-6 weeks), and convalescent (with gradual recovery over weeks to months). The most common complication and cause of death is secondary bacterial pneumonia, occurring in 13.2% of cases. Between 2000 and 2017, 307 deaths from pertussis were reported to CDC, mostly in children. Adults may also develop complications of pertussis, such as difficulty sleeping, urinary incontinence, pneumonia, rib fracture, syncope, and weight loss

c. Treatment required and level of medical treatment facility capable of delivering that treatment. Varying levels of supportive management are required, depending on severity of disease, as with influenza and COVID-19. Antibiotics are of some value if administered early (i.e., during the first 1 to 2 weeks of cough before coughing paroxysms begin).

d. Efficacy of available vaccine(s). Diphtheria, Tetanus, and Pertussis (DTaP) vaccine efficacy ranged from 80% to 85%, with overlapping confidence intervals.

e. Periodicity of vaccine boosters. Every 10 years.

f. Likelihood of infection if unvaccinated. Reported pertussis incidence has been gradually increasing in the U.S. since the late 1980s and early 1990s, and large epidemic peaks in disease have been observed since the mid-2000s. A total of 48,277 pertussis cases were reported in 2012, the largest number reported since the mid-1950s. Recent outbreaks of pertussis in the U.S. were due to low vaccination rates with large numbers of vaccine refusals (over 75% in one cluster) based on nonmedical reasons. The disease is more common outside the U.S.; an estimated 16.3 million people worldwide were infected in 2015, with 58,700 deaths.

g. Other methods of prevention, such as non-pharmaceutical interventions. For diseases transmitted by respiratory droplets such as pertussis, the CDC recommends non-pharmaceutical interventions (NPI) in addition to vaccination. NPIs recommended by the CDC to avoid contracting or spreading respiratory infections have been categorized as either personal or community based. Personal interventions comprise respiratory hygiene (covering the mouth and nose during coughing and sneezing), avoiding touching the face, frequent hand washing, cleaning and disinfecting objects and surfaces that are frequently touched, avoiding sick people, and self-quarantine when a person feels unwell. Community-based actions include public education through a variety of communication strategies, social distancing (6 feet), ensuring adequate ventilation of indoor spaces, and restrictions on public gatherings. The use of masks may be appropriate in certain situations such as during periods of high community transmission and when an individual or contact is immunocompromised.

h. Efficacy of non-pharmaceutical interventions. While we are not aware of any studies evaluating the efficacy of NPI specifically for pertussis, it is likely the effectiveness of most NPI would be similar to that for other infections transmitted by respiratory droplets.

(1) Despite the potential for NPIs to prevent respiratory disease transmission, there are very limited data available on their effectiveness at the individual level. Data on the effectiveness of NPIs implemented as community-wide mandates (where NPI impacts both source control and personal protection) would not be applicable at the individual level.

(2) In order to be effective, NPI must be implemented rigorously and continuously, and breaches in implementation are common. This is particularly true in communal environments such as aboard ships, in barracks, or in field situations; high rates of transmission have been documented in schools and household settings. One study during a recent mask mandate found that 90% of 5,893 individuals were observed not wearing a mask or not wearing it correctly, despite 75.9% of those individuals self-reporting always wearing a mask in public.

i. Medical opinion on whether non-pharmaceutical interventions, alone or in concert, will be successful in meeting the compelling government interest. Any combination of NPI in the absence of vaccination are not likely to be effective at preventing pertussis outbreaks and their resulting impact on the Navy's mission. Vaccination is not subject to reductions in efficacy due to incomplete implementation as with NPI. For this reason, and given the limited data available, it appears vaccination is significantly superior to NPI and mask wearing in particular, for preventing respiratory infections such as pertussis, especially when only implemented at the individual level and not by the entire community.

7. My point of contact is [redacted] Preventive Medicine, who can be reached at [redacted].

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