

CHRIS: Hello everyone. Welcome to this week's edition of the Osterholm Update COVID-19.

This week's podcast will address the topic, the use of masks to help reduce the spread of SARS-CoV-2. But before we begin, do you have any opening remarks you'd like to share with your audience?

MIKE: Thanks Chris. As anyone listening to this podcast during this first week of June knows, the Twin Cities community has witnessed the worst of times. Many would say the darkest times that have occurred in our modern history. The tragic murder of George Floyd has left us in a state of shock and pain. My deepest sympathy goes out to his family. And watching the subsequent widespread riots, looting, and destruction of property that has occurred in multiple locations of the Twin Cities leaves me saddened beyond words. I dedicate this podcast to all the victims of these tragic past days, starting with Mr. Floyd and his family and to all those who have suffered loss of property and goods here in Minnesota and around this very troubled country. The team at CIDRAP and I are only a few voices, but for all who have suffered, we're deeply sorry. May we find a way for the healing to begin.

CHRIS: Thanks Mike, all of us at CIDRAP echo your sentiments. As I just mentioned, this week's podcast addresses a much-discussed topic: the use of masks to help reduce the spread of the coronavirus. This is one of our most frequent email questions from listeners, so for this episode, we turn to our listeners to ask the question. Aaron asks, "What is the official CIDRAP viewpoint on the use of non-medical masks by the public? This issue is becoming so politicized lately that it is hard to find an unbiased, science-based answer. Should everyone be wearing some kind of face covering in public right now?"

MIKE: First of all, thanks Aaron, for that question. Let me just note that starting with this week, for the listener whose submitted question is chosen for the listener's question of the week, we will send them an inscribed copy of my newly issued paperback edition of *Deadliest Enemies*. The paperback edition has a revised and updated preface that includes information on COVID-19. So, Aaron we'll be back in touch with you to get your address and look forward to sending you the book.

I hope this discussion today about wearing masks, and specifically cloth masks in the community to prevent SARS-CoV-2 transmission, will be seen as constructive, practical, and, most of all, science-based. I'll be concentrating on the use of cloth masks, in that we're still working hard to preserve medical masks, meaning surgical masks, for healthcare worker use. Unfortunately, even these surgical masks are still in short supply for these workers. I will not be addressing the use of N-95 respirators, as they, too, must be saved for protecting our healthcare workers.

I understand both professionally and personally the urgency and fear many of you are feeling about how to protect your loved ones and yourselves from this virus. We all have a need for reliable, believable and safe answers. And just because we lack formal scientific evidence that something will protect us doesn't mean it won't. But that also means we just can't hope something will work. As my coworkers will attest, I often say, "Show me the data!"

This issue of cloth mask use has been one of the toughest COVID-related issues we've had to deal with, because much of the discussion and consideration of use hasn't been science-based but

rather heavily influenced by misinformation, emotion, and even partisan politics. I will lay out for you what I know and don't know about how cloth masks use can help decrease SARS-CoV-2 transmission and what they won't do. Understand that there is still important science-based information that we're lacking in order for us to give the public the information they deserve to make informed choices about protection, and for them to have an intelligent conversation about this issue with others.

I'm convinced we all want to do whatever we can to prevent COVID-19 cases and, specifically, empower ourselves to do what it takes to protect our loved ones and, of course, ourselves. I will adhere in this discussion to one basic principle; one that I have followed all my career: "When in doubt, just tell the truth." And if I don't know what I'm talking about, then I won't talk. I will do that here, even though I'm sure it will disappoint some of you who think I'm dodging a question when I simply say I don't know. In fact, as famed historian John Barry, author of *The Great Influenza*, the epic history of the 1918 pandemic has taught me, the cities that most successfully contained the 1918 pandemic had leaders who told the truth about what was happening and admitted when they didn't know.

We've heard wise advice from Peter Sandman and Jody Lanard in their recent outstanding CIDRAP Viewpoint report on crisis communication that the first priority must be, "Don't over-reassure in a crisis." Just tell people what you know and don't know. I'll try to do that today in a way that relies on the expertise of bona fide experts on this topic and our own careful review of the data regarding the effectiveness of cloth masks. I will share with you how I believe we got to where we are today. I will stick to the science, not emotions. First, let me be very clear: I believe

there may be a role for cloth mask use with this pandemic. I will discuss the context of how, when, where, and why that use might be warranted. As I just said, it's important to emphasize that the debate over wearing masks in the community centers on the use of cloth masks. Contrary to what has been written or stated, I am not against wearing cloth masks in the community. However, the public needs and deserves to know the science behind this issue, which I intend to lay out over the course of this episode. Currently there is inadequate information to answer critical questions about how well cloth masks protect anyone from being infected or infecting others. Remember that science is constantly evolving and answers to these questions may come with time. I will stick with the science of cloth mask protection and as new, reliable data becomes available. I will then update my conclusions and quickly share them with you. And most of all, my comments are in no way a statement supporting any partisan agenda regarding mask use or the COVID-19 pandemic in general. I just see myself as a scientific baseball umpire, making every attempt to objectively call the balls and strikes.

My daily inbox for several weeks has been overflowing with strongly held opinions of how I should be addressing cloth mask use. Some of these emails are incredibly thoughtful. Some are vulgar and threatening. All of them reinforce why the best science-based data has to serve as the roadmap for addressing this issue.

As a point of reference for our discussion, there are two quotes that I think capture the challenge that this issue poses:

First, “The greatest obstacle to discovering the shape of the earth, the continents, and the oceans was not ignorance, but the illusion of knowledge.”

Daniel Boorstin, a former librarian to Congress

Second, “For a successful technology, reality must take precedence over public relations, for Nature cannot be fooled.”

Richard Feynman, Nobel Laureate in Physics

I have been informed about the current situation by two specific events in my career; each taught me valuable lessons. Both of these events are discussed in my book, *Deadliest Enemies*. The first situation occurred in April 1984, when then Secretary of Health and Human Services Margaret Heckler and Bob Gallo, the co-discoverer of HIV, held a press conference announcing the discovery of HIV. Secretary Heckler also announced that day that we would have an HIV vaccine within 3 years; she seemed very certain of that. The next day I was asked by local media about the vaccine claim. Shortly thereafter other media also inquired about my take on the vaccine issue. Well as most of you know, I'm not a retrovirologist. I'm not an expert in that area, but I had spent a lot of time working with retrovirologists, people who truly understood HIV transmission. It simply did not make sense to me with what I knew about how the HIV virus was transmitted from one individual to another and how one's immune system might attack the virus, that we would have an effective vaccine anytime soon.

I responded to the media and my colleagues that, until we have a “beam me up Scotty machine,” or some kind of new breakthrough technology, I didn't understand how this vaccine would work.

My comments quickly made the rounds. Who was I to challenge people a lot smarter than me? I took tremendous criticism by groups who wanted to believe such a vaccine was just around the corner; that HIV would not be a major problem in the near future. As such, I was just a fear-monger and scaring people. My critical concern was that we couldn't let our guard down; we had to maintain all the efforts we were promoting to support people not to become infected through their personal choices of behavior. Shortly thereafter, I spoke at a Twin Cities meeting, and a group of gay businessmen were in attendance. When I was asked a question about the prospects for a vaccine, some of them got up and left in a very public display of their disagreement with my answer. Today I sit here in 2020, some 36 years later, and we're not close to having an HIV vaccine. I take no comfort in having been right about that. I just knew that I had to share that message to make clear to those at risk that a vaccine was not coming to rescue them soon. That just wasn't going to happen.

A similar situation happened in October 2011. We at CIDRAP and several other colleagues had extensively studied the effectiveness of influenza vaccine following the 2009 pandemic. We came to realize that much of the information about how well influenza vaccine protected us each year was seriously flawed. None of the flawed studies were intentional; rather, it had to do with the way these studies were conducted dating back to World War II.

It turns out that the serology testing—which detects antibody levels in the blood—used at the time could wrongly lead scientists to believe in more than 70% of cases that someone was

infected with influenza when they actually weren't. So a vaccine that was 0% effective could be shown to be 70% protective against flu.

It wasn't until about 15 years ago that we had new and better test methods available that could allow us to say, "Yep, somebody really is infected with the influenza virus." It was with studies using this new test that we realized that the vaccine effectiveness was much lower than had been widely reported. It wasn't 70% to 90%, as it had been promoted over and over again by public health and the medical community; but rather in a good year it might be 50%, and many other years it was far below that.

We published a paper in the medical journal *The Lancet* in October 2011 regarding this work; I was the first author. It had been previously rejected by the *New England Journal of Medicine* and the *Journal of the American Medical Association* as just factually wrong. When *Lancet* finally published it, you would've thought I had declared that influenza vaccine caused autism. I received many very painful emails from friends and colleagues, asking how I could sell out to the anti-vax crowd, and did I realize what my actions were going to do to the flu vaccine program? They claimed that many people would now not get this good vaccine and I'd be responsible for their infections and even their deaths. Remember the purpose of our work and paper was to tell the public and medical community about the shortcoming of the vaccine so we could inform the public of the accurate information, and most of all, use the information to urgently promote the need for better vaccines.

We owe it to the public to always tell the truth, and more important, not just tell them the truth, but provide information about fixing the problems we identify. As a result of our study, additional studies were conducted by others that confirmed our findings 100%. To the CDC's credit, they have been responsible for conducting a number of these studies and confirming our results. Today our 2011 findings are not even a minor controversial issue. We don't debate the fact that flu vaccines provide far less the protection than we wish they did. I still get my flu shot each year and encourage everyone to get theirs. Some protection is a lot better than none. With what we learned from our work and that of others is that we urgently need new, much improved influenza vaccines. And now, we have convinced the vaccine industry and governments that we must support major research on new and better flu vaccines, including ones we call universal flu vaccines. That was all I was trying to accomplish with our work, telling the truth and moving us forward to much better vaccines. But for up to several years that message made my life more difficult.

And now cloth masks. This issue of cloth masks has never been about me, it is about the message of cloth masks, and what they can do and can't do to protect us from SARS-CoV-2. Some people will be upset with me for what I'm about to share with you; so be it. My message is about trying to protect as many people as we possibly can from this virus until we hopefully have a safe and effective vaccine. I'm speaking the words into this recording microphone as if I'm talking to my family, my close friends, the people I work with at CIDRAP, and of course all of you too.

First of all, let me just say at the outset, I am not an aerosol science expert. I work with some of the best aerosol science experts. Theirs's is a very technical discipline; these experts have

tremendous experience in sophisticated laboratory air testing and have a detailed understanding of how respiratory protection devices work. They study how infectious agents spread in droplets and aerosols. The University of Minnesota happens to be blessed with some of the best aerosol science technology professionals in the world. And Dr. Lisa Brosseau, who is now a member our CIDRAP team and formerly with University of Illinois at Chicago and the University of Minnesota, is a recognized expert in aerosol science. She and her colleagues at University of Illinois at Chicago and others have helped us better understand the role that cloth masks can play in protecting us from SARS-CoV-2. Please know that the vast majority of information you're hearing every day in the popular literature or even in the news about cloth masks is not coming from anyone with any expertise in aerosol science. It amazes and disappoints me how many of my professional colleagues have no real understanding of aerosol science and the physics of respiratory virus transmission, but are very willing to present themselves to the media as such experts. It would be like if I were brought in to the computer science world and because I have a PhD in environmental health I could make apparent authoritative statements about computer science. A warning, you need to be very careful about who an expert is in this business. An MD or PhD in disciplines other than aerosol science or respiratory protection does not automatically make one an expert in these areas.

Another challenge we face with understanding masks and respiratory protection is the increasing number of poorly conducted and inadequately reviewed studies getting published in rapid succession. Some are even being widely distributed before they are reviewed and published. The media tends to jump all over them assuming they provide newly found and definitive answers about mask protection. There is real confusion about the differences between an N-95 respirator,

a surgical mask and a cloth mask, or as some call a face covering. The term medical mask has been used in many different ways. Some of the most dramatic statements about mask protection have been based on studies that included a small number of people. The authors of some of these studies make claims about their findings that are extrapolated to the world. Or there are the modeling studies, which by now most of you have grown accustomed to appreciating their unreliability in predicting the number of new COVID-19 cases and deaths. I celebrate whenever a well-conducted study is published regardless of whether it's findings support 24/7 mask use or demonstrate the limitations of certain mask use practices in COVID-19 prevention. I just want reliable data, derived from well-conducted studies to form my best professional opinion.

I will tell you what I have learned from the real experts. To better understand this complicated issue, let me quickly walk through the history of prevention recommendations since January 20th, when we first declared at CIDRAP that we were very likely to experience a pandemic of SARS-CoV-2 virus around the world. By the way, we recognized very early on the challenge that this pandemic was going to represent in terms of respiratory transmission. Granted, we didn't know at first the extent of which respiratory transmission would occur and how it would occur in terms of droplets versus the issue of aerosols. We just knew that this was a highly infectious agent.

Remember that when we breathe, we actually exhale out particles. We talk about them as droplets or as aerosols. Really they're one continuum of size, they're not A or B. It's like a rheostat rather than a light switch that is turned on and off. When we breathe, our resting breath rate is about 6 liters per minute, and we exhale about 500 particles per liter, most of them aerosols. These are the tiniest of particles. So in a minute, we put out about 3000 particles into

the air around us. If one wants to understand what an aerosol is, think about the last time you saw sunlight coming through the window in your house, and you saw all that dust floating in the air. You say, "oh my, I have a dusty house". Those particles you are seeing are aerosols. They are free floating particles that can occur just from breathing. If I'm in a room speaking, within minutes that room becomes filled with these small floating particles from me even though no one may see them or feel them. And if you're in that room, you're going to both exhale your own particles and you are going to inhale my particles. The transmission of a respiratory pathogen via an aerosol versus a droplet is a game changer in terms of the level of protection required. Remember that droplets are those particles that come largely from coughing and sneezing. Think of them as the boulders and aerosols as the marbles.

In the earliest days of this pandemic we knew that breathing air would be the main way the virus would be transmitted. We believed that there was a likelihood that this virus might be an aerosol transmitted virus, as we know definitively happens with influenza. Those who do not yet believe that influenza is transmitted by aerosols are just not current with the large body of scientific information available that shows just that.

So, let's just take a brief history journey with regard to SARS-CoV-2 transmission and where we are with this issue. On January 23rd The New York Times had a story entitled "Many in China Wear Them, but do Masks Block Coronavirus?" This was really one of the first journalistic efforts in which the public was provided information about masking. The chairperson of the public health committee for the Infectious Disease Society of America, the major organization

for infectious disease professionals, was quoted as saying "surgical masks are really the last line of defense." She went on to say, "we worry about people feeling they're getting more protection from the mask than they really are. Because surgical masks aren't fitted or sealed, they leave gaps around the mouth so you're not filtering all the air that comes in." Again, the Infectious Disease Society comment was about surgical masks, not cloth masks.

On February 29th, U.S. Surgeon General Dr. Jerome Adams tweeted that masks do not offer any benefit to the average citizen in preventing SARS-CoV-2 transmission. He tweeted, "Seriously People Stop Buying Masks. They are NOT effective in preventing general public from catching #Coronavirus, but if healthcare providers can't get them to care for sick patients, it puts them and our communities at risk!" Dr. Adams was referring to surgical masks, not cloth masks

And then, on March 3rd, The Cochrane Clinical Answers, an organization that does reviews of medical issues that considers all the information that has been published about a given topic, published a report, "Can Physical Interventions Help Reduce the Spread of a Respiratory Virus?" The Cochrane approach to reviewing topics applies standards of review and determine whether the data are of high, moderate or of poor quality. They concluded that the evidence suggests that some physical interventions may reduce the spread of respiratory viruses, particularly hand washing, wearing of masks, gowns, and/or gloves, but most evidence is of very low certainty. Again, the masks assessed here were surgical masks, not cloth masks. The Cochrane reviewers went on to say that the results are not consistent across all studies and reviewers classified the evidence as very low certainty. So, at that point, their review results did not provide strong

evidence to support that you should use surgical masks to reduce the spread of respiratory viruses.

Information on how SARS-CoV-2 is transmitted also continued to come forward. On April 1st, the National Academy of Medicine, which had established a rapid COVID-19 expert consultation committee was asked to review the possibility of a bio-aerosol spread of SARS-CoV-2 for COVID-19. Of note, The National Academy of Medicine provides national and international advice on issues relating to health, medicine, health policy, and biomedical science. It aims to provide unbiased, evidence-based, and authoritative information and advice concerning health and science policy to policy-makers, professionals, leaders in every sector of society, and the public at large. The Academy expert committee responded with the following; “While the current SARS-CoV-2 research is limited, the results of available studies are consistent with the aerosolization of viruses from normal breathing.” They went on to support the fact that this could be a viable means of transmitting this virus to humans, providing more reinforcement that what we were now beginning to see was that aerosol transmission of this virus is very important. You'll get a sense in a moment why this becomes a critical consideration with regard to the effectiveness of cloth masks with SARS-CoV-2 transmission.

On April 3rd, the CDC published a document that had been anticipated following statements by White House officials the week before its release that such a document would be forthcoming. The document entitled, "Recommendation regarding the use of cloth face coverings, especially in areas of significant community-based transmission," stated that “In light of this new evidence, CDC recommends wearing cloth face coverings in public settings where other social distancing

measures are difficult to maintain (e.g. grocery stores and pharmacies) especially in areas of significant community-based transmission.” The new evidence the document was referring to was investigation reports and studies demonstrating presymptomatic or asymptomatic transmission. The recommendation was published without a single scientific paper or other information provided to support that cloth masks actually provide any respiratory protection. There were seven reports or papers listed as “Recent Studies” that detailed the risk of presymptomatic or asymptomatic transmission. There was nothing about how well such masks protect against virus transmission, particularly from aerosol-related transmission.

Never before in my 45 year career have I seen such a far-reaching public recommendation issued by any governmental agency without a single source of data or information to support it. This is an extremely worrisome precedent of implementing policies not based on science-based data or why they were issued without such data. I understand recommending prevention measures in the face of a dangerous pandemic even when data may be lacking; applying the John Snow approach to pulling the pump handle has been at the very core of my public health career. Yet the precautionary principle that emphasizes caution, pausing and review before leaping into new interventions must also be considered. If these cloth masks do little to reduce virus transmission due in large part to their lack of protection against aerosol inhalation or exhalation, do we not have an obligation to tell the public of this potential limitation? How many cases of COVID-19 will occur when people using cloth masks and not understanding the limitations of their effectiveness participate in activities with others where virus transmission does occur? I believe this cloth mask recommendation situation represented the other low point in CDC’s response to COVID-19 with the other being the failed testing situation. I have talked to close friends and

colleagues who work at CDC and who were involved on the periphery with this issue. They universally disagreed with the publication of this recommendation based on the lack of information supporting that cloth masks actually reduced the risk of virus transmission to or from someone wearing a cloth mask. The CDC recommendation document states that CDC continues to study the spread and effects of the novel coronavirus across the United States. When people state that CDC recommends cloth face mask use you have to understand there was much more going on than science and public health protection with this recommendation. I urge you go online to the CDC website yourself and you'll not find one piece of information supporting that cloth masks are effective in reducing respiratory virus transmission. Ironically, what you will find is that the National Institute for Occupational Safety and Health, an institute that is part of CDC, states on the CDC site the following; "A surgical mask does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection"; and "that leakage occurs around the edge of the mask when the user inhales." One must logically ask, how can one part of CDC state that surgical masks do not provide adequate protection against aerosol exposure and then another part of CDC states we should use cloth masks to provide community protection from SARS-CoV-2 even though we know cloth masks are less effective in reducing the inhalation or exhalation of aerosols than are surgical masks. And remember that NIOSH is recognized as one of the world's leading authorities on respiratory protection. Frankly, I believe that this issue of CDC recommending the use of cloth masks without any substantial scientific evidence that they provide such protection, and in conflict with their own expertise in NIOSH, has helped create the immense confusion that exists around this issue. In short, I believe that CDC has failed the public by creating this confusion. And their lack of reconciling this confusion is the second of the agency's major

failures with their response to this pandemic. Regular listeners to this podcast know that I have supported CDC and their performance against many unfair and baseless accusations during this pandemic. But their failure to provide the leadership and clear, science-based messaging with this issue continues to be terribly unfortunate.

Of note, shortly after CDC published their recommendation U.S. Surgeon General Dr. Jerome Adams changed his “do not use surgical masks recommendation” to one supporting the CDC cloth mask recommendation. Again with no new data on how cloth mask use reduces the risk of virus transmission. This gives one pause to understand the credibility of a U.S. Surgeon General’s science-based recommendation going forward.

On April 6th, just a few days later, to confuse matters, the WHO came out with their interim guidance on the use of masks in the context of COVID-19. By the way this is still their current recommendation. The recommendation reads, and I quote, "there is limited evidence that wearing a medical mask by healthy individuals in households, or among contacts of sick patients, or among attendees of mass gatherings, may be beneficial as a preventative measure. However, there is currently no evidence that wearing a mask, whether medical or other types, by healthy persons at a wider community setting, including universal community masking can prevent them from infection with respiratory viruses including COVID-19.” This recommendation is not just about surgical masks, which they're calling medical masks, but also cloth masks.

On April 8th, there was another rapid expert consultation by the National Academy of Sciences; it specifically addressed the effectiveness of fabric (i.e. cloth) masks for the prevention of

COVID-19. I was a member of this group. I went into it with open mind to understand the scientific data that were available to address this request. Like everyone else, I'm always looking and hoping for the magic bullet. The conclusions of this committee were unanimous. They were; "There are no studies of individuals wearing homemade fabric masks in the course of their typical activities, therefore we have only limited and indirect evidence regarding the effectiveness of such masks protecting others when made or worn by the general public on a regular basis. The evidence comes primarily from laboratory studies testing the effectiveness of different materials at capturing particles of different sizes. The evidence from these laboratory filtration studies suggest that such fabric masks may reduce the transmission of larger respiratory droplets, but there is little evidence regarding the transmission of small aerosolized particulates of the size potentially exhaled by asymptomatic or presymptomatic individuals with COVID-19. The extent of any protection will depend on how the masks are made and used. It would depend on how mask use affects user's other precautionary behaviors, including their use of better masks when those become widely available. Those behavioral effects may undermine or enhance homemade fabric masks overall effect on public health. The current level of benefit, if any, are not possible to assess." This conclusion remains the position of the National Academy of Medicine.

On April 19th UNCOVER, the Usher Network for COVID-19 Evidence Reviews located at the University of Edinburgh, a very highly respected objective data review group like the Cochrane organization, issued a report on the effectiveness of homemade masks. They asked; "Does the use of face masks by the general population make a difference to the spread of infection?" They reviewed in detail the quality of evidence on face mask effectiveness and determined it is mixed

and low quality. The conclusion, and I quote, "mask wearing alone, in the absence of other preventative measures, is unlikely to be effective, yet most studies do not take this into account."

On April 21st a statistical model was made public with great fanfare by a group of five researchers, none of whom have expertise in aerosol science or respiratory protection concluding that universal masking should be made mandatory to significantly reduce SARS-CoV-2 transmission. They determined in their model that if 80% of the population used cloth masks COVID-19 incidence could be reduced to one twelfth of what it is today. The lead author is De Kai, a computer science expert. We've looked carefully at the underlying assumptions of this model. It's known as the SEIR model: the susceptible, exposed, infectious, recovered model. This is a generic modeling tool used by many in public health. Several of my colleagues with significant modeling expertise have examined the De Kai model and found it has serious flaws in its assumptions and exposure parameters. For example, it does not take into account dose or time contact, supporting the conclusion that the authors have a very poor understanding of the critical issue of aerosol versus droplets exposure, and what a cloth mask can do to limit such exposure. Because a cloth mask is not tight fitting, the aerosols escape out of the masks with each breath. This paper has not yet been published, but it has been widely promoted around the world. And as you will learn in a minute, the results of this modeling study has been the basis for people making major policy decisions about requiring the use of cloth masks despite all the other cloth face mask reviews that have been conducted and that I have summarized for you already. Unfortunately to criticize, De Kai's group's efforts has meant being on the receiving end of the wrath of people who believe its findings to be the only means of stopping the COVID-19 pandemic. This paper and how it is being used by advocates of cloth masking reminds me very

much of what I dealt with regarding the blind support for the 70-90% effectiveness of influenza vaccine.

On May 14th, Jeremy Howard from the University of San Francisco, who is a data scientist, and teaches courses online in machine learning, became interested in masking and the COVID-19 pandemic. He published an article in The Conversation and formed a group called MASKS4ALL. Ironically, The Conversation is supposed to be an independent source of news, analysis and expert opinion, written by academics and researchers, and delivered direct to the public. The leadership of The Conversation states that in a world of misinformation and spin, The Conversation contributes to healthy democratic discourse by injecting facts and evidence into the public arena. I surely challenge the premise of The Conversation as you will understand in a moment.

Howard stated in The Conversation article that based on the findings from the model by De Kai and colleagues, mandatory masking with cloth masks could be amongst the most powerful tools to stop the community spread of COVID-19. This statement was not supported by any peer-reviewed data. He has also stated publicly that he has identified 34 papers showing the effectiveness of cloth masks and none that show otherwise. Such a statement is totally baseless and is in my estimation very reckless. Nonetheless his position has become the prevailing norm in the public understanding of the effectiveness of cloth masks. What was most telling to me, was that on May 13th MASKS4ALL issued a public letter, which was signed by an international group of self-identified medical experts about the need to require mandatory cloth face masking across the board. Their position was that because people are most infectious in the initial period

of infection when it's common to have few or no symptoms, cloth masks are important in obstructing a high proportion of the droplets from the mouth and nose that spread the virus and that's why they should be used. Remember that droplets come largely when people cough and sneeze. In other words when they are clinically ill. As everyone knows, individuals who are clinically ill should not be out in the public, mask or no mask. The aerosols, which are exhaled even when not symptomatic are coming out of the sides of the cloth and surgical masks that are not tight face fitting. The cloth that serves as the filtration for the mask is meant to trap particles being breathed in and out. But it also serves as a barrier to air movement because it forces the air to take the path of least resistance, resulting in it going in and out at the sides of the mask. I'll come back to that.

The MASKS4ALL letter I just referred to states that non-medical masks (i.e. cloth) have been effective in reducing the transmission of coronavirus. This claim has only been evaluated in three studies involving cloth mask use in the community; all were conducted during the 1918 influenza pandemic. All three studies concluded that cloth masks did not reduce the incidence of influenza. There are no such studies conducted that use surgical masks in an experimental setting with SARS-CoC-2. The bottom line is that this MASKS4ALL letter makes it look like there is a body of data supporting cloth mask use that doesn't exist. This same group claims that places and time periods where mask usage is required or widespread have been shown to substantially lower community transmission of SARS-CoV-2. In fact, in countries experiencing COVID-19 outbreaks many other control measures were put in place at the same time that mask use may have increased. I believe their example for the impact of cloth masking reflects the age-old elephant sign phenomenon; I can declare to you with all sincerity that when I put a sign in my

front yard in the Twin Cities area years ago that no elephants are allowed, guess what happened? Not one elephant has showed up in my front lawn since I put up that sign. Not one. And this is the same phenomena that occurs with saying mask use was responsible for stopping widespread SARS-CoV-2 transmission in countries that were putting into place a myriad of control measures such as widespread testing, extensive contact tracing programs and quarantine measures. Finally the MASKS4ALL group claims that laws appear to be highly effective in increasing compliance in slowing or stopping the spread of COVID-19. There is simply no credible data to support the claim.

What was even more telling, regarding the MASKS4ALL letter was the fact that over a hundred prominent experts called for this mask requirement. I contacted five of them who I know well, all are close friends. Four of them were “surprised to shocked” when I shared the information I just with shared with you regarding the body of data or lack thereof, supporting the effectiveness of cloth masks in preventing viral respiratory-transmitted agents. They had just assumed that the summary information was accurate. The fifth one was honest enough to say to me, “Well, I signed it because of pressure from peers.” I don't know how many of the other signers of the letter had a similar experience. Regardless, this is not the way you make science-based public policy on such a critical issue. I hope if nothing else “so-called” experts on the various issues related to COVID-19 learn to stay in their professional lanes or take it upon themselves to get the facts before making statements of critical public policy importance.

And the credible information challenge continues on. On May 24, the New York Times had a Sunday editorial, “The Most Patriotic Thing You Can Do Right Now.” It was an editorial about

how "our nation is rising, however imperfectly, to meet the challenges posed by the coronavirus pandemic". That needs to be said more often. But what was very troubling is that they included the following statement in the editorial: "Millions of Americans now routinely wear masks when we go outdoors, a group effort that was inconceivable just weeks ago. Today nearly two-thirds of Americans agree that masking is a matter of public health. The science, while still evolving backs that up." There is a link in the editorial to support the science statement, and it is a May 8th article in Vanity Fair, for which the article cites as its primary expert source the data from the yet unpublished De Kai model that I just shared with you earlier. Remember that model is extremely problematic from a scientific validity standpoint. Now the New York Times is buying into this misinformation without any serious editorial review process. This was ironic in that I've had three op-ed pieces on COVID-19 in the New York Times in recent weeks. All three of them were meticulously researched by my coauthor Mark Olshaker and me. We spent many days writing and rewriting the pieces per the extensive editorial review and fact checking by the Times' editors. For the one we did on testing we had over 20 drafts and had to support every word in the op-ed with scientific data, not by some general readership article in a popular entertainment magazine describing a yet to be peer-reviewed statistical model. The fact that the New York Times would have such a different standard for its own editorials compared to what they require of others writing op-ed pieces is unfortunate. The Times' use of the Vanity Fair article as the basis for their conclusion stated regarding cloth mask use is extremely disappointing and feeds into this "crowd mentality of dealing with cloth masking for all."

Finally, regardless of all the "yes, the use of cloth masks offer critical protection to users" or "no they don't" statements, there is the fact that only one study has been conducted that was a

randomized trial of cloth masks compared with surgical masks. It was carried out in healthcare workers, not the general public. In short, the study found that those that wore the cloth masks had 13 times more infection outcomes than those that wore surgical masks. The authors of this study also found that cloth mask users versus the surgical mask users had a 6.6 times higher risk of influenza-like illness and 1.7 times higher risk of a lab-confirmed respiratory virus infection. The filtration testing of the surgical mask material found a penetration rate of 44%, meaning that 44% of the particles came through the mask and for the cloth mask it was 97%. This means that in the filtration studies only 3% of the particles in that test were stopped by the cloth material. The authors concluded that cloth masks should not be recommended for healthcare workers, particularly in high-risk settings. If they are not recommended for healthcare workers per the result of this study, the only one ever done comparing surgical and cloth masks, how can cloth face mask use be expected to reduce the incidence of COVID-19 to one-twelfth of what it would otherwise? Again this is the figure as stated by Kia and Howard. Remember, that's what the highly touted results of the De Kai model determined. Honestly, this is the kind of magical thinking that only confuses the public and should not be left unchallenged. We owe the public much more.

I have just provided a bit of the journey we have been on with regard to the use of cloth masks as a public health tool in fighting this horrible pandemic. My purpose was not to prove a conclusion about the effectiveness of these masks but rather to give you a sense of how dysfunctional our process has been in using scientific data to have a rational and fact-based process for determining how we protect our family, friends and colleagues. Why have all the reviews of cloth mask performance by groups such as Cochrane, UNCOVER, the National Academy of Medicine and

WHO been left out of the national discussion? Why hasn't someone highlighted the lack of data provided to support the CDC recommendation or challenged the MASKS4ALL misinformation campaign?

For all that the media has done to shine a light on the many complex public health, medical, economic and public policy issues related to COVID-19, the fact they have not done a more comprehensive review of this issue is unfortunate.

Let me just repeat, I'm doing this podcast to tell you the scientific truth the best I know it, and to help you better understand what you can do to protect your family and yourself against SARS-CoV-2. One of the things that may help you understand this recommendation dilemma is to better understand what we're talking about by masks. The N95 respirator is that tight, face fitting respirator that basically greatly limits the virus from coming in the loose-fitting sides of the mask. That's why men with a beard, or even beard stubble can't wear them and be effectively protected. All users have to be fit tested to make certain they have the right mask size for their face. A tight face fit forces the air you are breathing in or out to come through the mask material which has an electrostatic charge which traps the viruses. Surgical masks do not do that. They have gaps on the side. They do have a material that may capture droplet particles that are coughed or sneezed out. But, when you think about this issue, remember that surgical masks just don't fit tight to your face and there's no requirement they fit. I think most people would be surprised to learn that even though their purpose was to prevent surgeons from dripping their secretions into the incision on someone in a surgery, there have been three clinical trials of surgical masks and how well they do that and none of them have shown any difference in wound

infection rates whether the staff were wearing masks or not. So, they're not even that effective for what they were intended.

If you want a good example of how important mask fit is, think about a swim mask. You are going swimming in the pool. You put on your mask and dive in. The mask suddenly fills with water. None of that water comes through the glass lens. It comes through the seal between the mask and your face. And that factor is why there is such a serious concern about how well a cloth mask will stop someone from breathing out an infectious aerosol and it escaping in a large volume through the loose face fit seal. Similarly, there is a concern that aerosol-filled air will be inhaled even with a cloth mask.

So what do I conclude regarding the use of cloth masks in the community?

First, it cannot be overstated, that the most important thing someone can do to protect themselves from becoming infected with SARS-CoV-2 is to maintain as much distance as possible from other people who you are not living with. While it has become a common recommendation that a six foot distance is sufficient to eliminate the risk of inhaling infectious particles, we know that infectious aerosols can travel further distances, particularly indoors.

Second, the cloth face mask recommended for use by virtually everyone making such recommendations are not surgical masks or N-95 respirators. These critical supplies must continue to be reserved for healthcare workers and other medical first responders, as recommended by current CDC guidance.

Third, the preponderance of scientific evidence supports that aerosols play a critical role in the transmission of SARS-CoV-2 and that evidence is growing almost daily. Any respiratory protection respirator or mask must provide a high level of filtration and fit to be highly effective in preventing the transmission of SARS-CoV-2.

Fourth, the public message on cloth mask effectiveness that is provided to the medical community, public policy leaders and the general public must be based on sound scientific data and currently it is not. We have an urgent need for detailed information on the effectiveness of cloth masks in preventing SARS-CoV-2 transmission as it relates to mask construction and the impact of exposure factors including the concentration of the virus in the inhalable air and the length of time of exposure. This should be CDC's job with expert support from NIOSH. To date that has not happened. Therefore, CIDRAP is currently working with a group of international experts in respiratory protection to determine the relative protection of cloth masks based on modeling of air movement with mask construction, virus infectious dose and time of exposure. We will share this information with the public as soon as we have completed it.

Fifth, many in the general public are currently using cloth masks in public to protect themselves and others. They should be made aware that these masks may provide some benefit in reducing the risk of virus transmission, but at best it can only be anticipated to be limited. Distancing remains the most important risk reduction action they can take. I understand why many would argue that some benefit is better than none, but I believe that we must approach this assumption with caution. The messaging that dominates our COVID-19 discussions right now makes it seem

that if we are wearing cloth masks you're not going to infect me and I'm not going to infect you. I worry that many people highly vulnerable to life-threatening COVID-19 will hear this message and make decisions that they otherwise wouldn't have made about distancing because of an unproven sense of cloth mask security. Distancing remains the most important risk reduction action we can take.

So, where are we at on this? It's terribly unfortunate that this situation has become such a divisive issue. As I said in a previous podcast, I now understand what it must've been like during the Civil War to be a mother or a father in a family where half of their sons fought for the North and half of their sons fought for the South; I see and feel this division today. In all my years in public health, I've never experienced this blowback, even with the influenza vaccine or HIV vaccine related issues. We've actually had people who've contacted funders of CIDRAP, demanding that they defund us, because of my position on cloth masking. The leadership at the University of Minnesota has received complaints about me and the position I've taken. I've had four e-mails just this past week from physician colleagues who wanted me to sign onto their petition to mandate that everyone wear a cloth mask in public. I see organizations that are now supporting this effort without any real understanding of the evidence for making such a recommendation. Two such organizations are major medical clinics in this country. I contacted close colleagues in both clinics and sought information on the how the decision was made to support a community-wide routine cloth mask recommendation. Both said that once CDC recommended it, they had no choice. They did not undertake a review of the mask effectiveness

data themselves nor did they consider any of the other reviews that had been done on this topic as I have covered previously. And you know the basis for the CDC recommendation.

Some important additional points I want to make on mask use; first, I see many people wearing masks inappropriately, meaning they're not over the nose and they are so loose fitting that the air being breathed in or out can go right up or down underneath the mask. We need to do a much better job educating people on how to wear masks if there is to be any benefit. Cloth masks when worn as I just noted are certainly worthless. I've even seen many prominent individuals on TV in the past week, with their mask on and not over their nose. It's really important that if we're going to use cloth masks, they need to be tight face fitting. And yes, I use a cloth mask in public places, even if I'm not convinced it's going to make any real difference in protecting me. I do it because I don't want to make other people feel uncomfortable if they see me without one. This is the new unfortunate culture of mask shaming. Please, this shouldn't be about politics, this should be about public health and science.

And remember that facts matter, so when you hear, based on this particular podcast, that Mike Osterholm said this or Mike Osterholm said that, you know what I said. I have read some of these quotes I never said but are attributed to me and I do say to myself, "who is this guy?"

And last, I want to report that I do have hope in the role that masks may play as a critical weapon for the public to take on COVID-19. I'm working with a group of some of the country's most renowned technology leaders to develop a reusable N95 mask that could be washed hundreds of times without losing its electrostatic charge and fit. These will be provided to the public. This

group is led by John Doerr, Bill Joy and Michael Zimmerman. If these masks can become a reality and many, many millions of them made and distributed to the public around the world in the next few months, this could be a real game changer. So anyone who claims I don't think masks are important, they are just plain wrong. I do. In fact I think about it frequently as my daughter, who is a neonatologist, goes to work every day to a potential COVID situation. I think about that all the time.

I hope this podcast has been helpful to you in understanding the cloth mask journey. I know it's been long, I apologize for that, but I think it's important you understand that this issue has been captured by a few non-expert individuals and many people in the public health and medical communities have unsuspectingly jumped on board, because they thought that was the right thing to do. I'm very disappointed that the public health community has let you down by not providing clear and accurate information on what cloth masks can do and can't do to protect you and your loved ones. This clearly should have happened before the launch of international campaigns to make mask usage mandatory. We all need to know what protection these masks afford us and educate the public about those findings as soon as possible. CIDRAP is actively working to fill this gap in information. In the meantime I have concerns that we may very well be putting people in harm's way to this virus by not giving them clear messaging about what cloth masks can and can't do to reduce one's risk of infection.

When you wear your cloth mask in public, realize that it may only provide very limited protection. The most important thing that you can do to protect yourself and others is distance.

One thing you must not forget in all of this, is that no matter how complicated this issue is, or whether you agree or not, let's come together to take on this pandemic with our podcast audience's powerful epidemic of kindness. Be kind, particularly in these turbulent times. In fact, if you get into a discussion on masks, think of it first as facts and then information sharing with kindness.

Finally, in the words of one of the greatest philosophers of our time, Winnie-the-Pooh. Please never forget, "You're braver than you believe and stronger and smarter than you think."

Thank you.