Dr. Alejandro Cravioto

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Marianne O'Hare: Welcome to Conversations on Health Care with Mark Masselli and Margaret Flinter, a show where we speak to the top thought leaders in health innovation, health policy, care delivery, and the great minds who are shaping the health care of the future.

This week, Mark and Margaret speak with Dr. Alejandro Cravioto, Chair of SAGE, the Strategic Advisory Group of Experts on Immunization. Reporting directly to the World Health Organization, SAGE just issued an emergency authorization for global distribution of the Pfizer Vaccine for COVID-19. Dr. Cravioto talks about the need for more scaled up production and distribution of approved vaccines and the need to ensure that distribution of vaccines is fair and equitable around the world.

Lori Robertson also checks in, the Managing Editor of FactCheck.org, who looks at misstatements spoken about health policy in the public domain, separating the fake from the facts. And we end with a bright idea that's improving health and wellbeing in everyday lives.

If you have comments, please email us at chcradio@chc1.com, or find us on Facebook, Twitter, or wherever you listen to podcast, and you can also hear us by asking Alexa to play the program. Now stay tuned for our interview with Dr. Alejandro Cravioto here on Conversations on Health Care.

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Mark Masselli: We are speaking today with Dr. Alejandro Cravioto, Chair of SAGE at the World Health Organization, the Strategic Advisory Group of Experts on Immunization, the principal advisory group at the WHO on vaccines and immunizations, which just gave emergency authorization for the Pfizer COVID-19 vaccine for global distribution.

Margaret Flinter: Dr. Cravioto has worked to advance nutritional protocols for children all around the world. He served as Dean of the Medical School of the National Autonomous University in Mexico City. And he's been the Executive Director of the International Center for Diarrheal Disease Research in Bangladesh. Dr. Cravioto, welcome to Conversations on Health Care.

Dr. Cravioto: Thank you very much.

Mark Masselli: You know, the world has entered this second year of the COVID-19 pandemic and no one, including the World Health Organization, could know how far this emerging pathogen would reach when it first began. But we're at this turning point. Your team at SAGE just issued a green light for the global distribution of the Pfizer COVID-19 Vaccine. And I wonder if you could tell our listeners about the recent

emergency authorization of this particular vaccine, which had already been approved for use in several countries. But what criteria did your team at SAGE consider before making your recommendation?

Dr. Cravioto: Every time we have a vaccine to evaluate, it has to be a vaccine that has already gone through the whole regulatory process. That means FDA or the EMA in Europe, or where the vaccine was produced, how it is produced. Now what the WHO does is look at the vaccine in the same way, in two ways. One, it goes through what is called a prequalification, which allows countries that don't have a regulatory authority of themselves, to use that as a way of saying this is a safe vaccine to use in our population. Or, it allows the UN agencies, UNICEF and others, GAVI, to buy the vaccine, to purchase the vaccine that is available.

So, on the other hand, for the policy part, in 1999, the Director General decided to create a group of experts that would look at all the issues related to vaccines and immunization. The idea that 15 of us that represent the world geographically and also have a total gender balance, that means half of men, half women, look at the evidence that was handed in to the regulatory authorities, not only the qualities of the vaccine, but how the vaccine should be used. Vaccine is not useful unless it goes into somebody, orally or injected.

So in that sense, what we do is to review the evidence. And for that we create what we call a 'working group'. To extend the expertise of the 15 of us, we invite others to participate also, selecting people from all over the world, in these working groups. And in this case, we have a wonderful one, of 26 people from around the world who have been helping us three times a week. And this group has been looking at three areas. One is the evidence, one is how the vaccine should be prioritized for use, and the other one helps us with the modeling. How do we actually try to see how this vaccine will work through this mathematical modeling that allows us to predict a bit how these things would work.

Margaret Flinter: Well Dr. Cravioto,I think we're really curious. This was such an intense race to develop a viable vaccine, and truly it does sound like a very cooperative venture, and yet we know we had scientists working all over the world, just on the basic science to develop the vaccine. Was there that level of collaboration in the scientific community about the actual development of the vaccine as well, and how does the World Health Organization help facilitate that, since this is obviously also a huge business proposition for these companies?

Dr. Cravioto: I think here, what we have to see, and we see that very much in vaccines, is a public-private partnership. In many cases, we have vaccines that are very good, but there's no commercial value in them. Now, somebody might decide to produce it because it has public

good, but that doesn't necessarily happen with all the vaccines that are actually created. So we have what we call this 'valley of death'. That means the vaccine just gets lost, because no one is willing to put up the money. If you look at Warp Speed, the program in the US to speed up the process of vaccine, what they put their money in was not the development of the vaccine, that was done by Pfizer, by Moderna, by AstraZeneca, by each one of the companies. What the US put the money for was to create, at the same time that the vaccine was being developed, a factory to produce it.

Now, normally, that is, two-three years after the vaccine has been approved, after it has gone through SAGE and every single committee. Then somebody puts up the investment to create the whole area to produce it. This is what has been incredible with these vaccines that we have, not knowing that the vaccine would actually work, have invested the money to put up a factory to produce it. So as you saw in the US, the FDA approved the vaccine one day, and the next day it was rolling out of the factory where it was being produced, long before the whole process of approval started.

The other is that we can shorten the time of these long trials that we do, without affecting the safety or the efficacy of the vaccine. And that's something we really need to learn to do it more quickly. We have a wonderful vaccine for tuberculosis that is in development, and the prediction is that we won't have the product until probably 2028-2030 because of all these issues related to the development, and the testing, and the production of a vaccine, which might be of great help to the world, and needs to be moved in a faster way.

Mark Masselli: You know, we recently had Dr. Paul Offit join us. He serves on the committee advising the United States for vaccine approval and, like you, they had to mine trial data very thoroughly before they made their recommendation. And yet, there are a number of other vaccines in the queue, one from AstraZeneca, another from Russia, China, India. Each has its own configuration, and I'm wondering if you could talk to us about your access to this data to these emerging vaccines. What are you doing at Sage to monitor safety and efficacy?

Dr. Cravioto: Well, SAGE has always worked very openly with the producers, both the ones that are established in the higher income countries, but also the ones that are housed in the lower or middle income countries. And now we have large producers, especially in India and in China, that have come online, which have been very helpful to have a much wider amount of types of vaccines. So what we do is, this is a voluntary process, any company that wants to come to us, or to WHO, with the data, the dossier, like they hand it in to the FDA or the EMA, does it. And then it goes through the process, as you have seen with these new ones of looking at the data, and when the whole thing is

completed, then it comes to SAGE for review, and then we decide whether the vaccine has all the characteristics needed to make a recommendation. Our recommendations go to the Director General of the organization, who then if he agrees, approves them, and then they're disseminated both through the World Health Organization and through other systems.

What we also want to see as part of what we review is how is this vaccine going to be used. With the Pfizer vaccine, our biggest problem was how are we going to maintain a cold-chain to be able to keep the vaccine safe, which requires a -70 temperature. But we have done this in the past. We have vaccinated over 300,000 people in the Democratic Republic of Congo against Ebola using a vaccine that also requires a -70 temperature to keep it alive. So we have done it before. And in my own country when people say well how are we going to handle these? Research centers have -70 freezers, so they lent them to us to set up vaccine centers where we now move the people to them, instead of moving the vaccine towards them.

So all these things have the proposal that a vaccine should be used effectively, not get lost in the way, because that is what really decreases its efficacy. In the case of the vaccines for COVID, we have seen the Pfizer dossier, we have looked at Moderna and we have had close to five or six long sessions with the producers, with a working group. They have presented the data. We have made questions to them, they have answered the questions. So we now have a confidence of the information that we're handling, to be able to make the recommendations for these other vaccines, as we have done for the Pfizer.

Margaret Flinter: Wow! such great progress. And I know, because of all the work that you've done with the World Health Organization, and internationally, you're concerned with making sure that we use the vaccines effectively, but also with using them equitably around the globe and making sure that it's not the wealthier nations that disproportionately take the vaccines than the less advantaged countries. You have COVAX as part of the World Health Organization, which addresses this issue of vaccine nationalism, and we really welcome you telling us a little more about that.

Dr. Cravioto: This is a wonderful initiative, mainly based on the whole idea of the Global Alliance, what we call GAVI. GAVI is a system of input of money from private funders, the Gates Foundation, others, and governments, who actually come together to make sure that countries that have less income, are also capable of having a good vaccination program. Over the years, GAVI has supported countries in Africa, Latin America, in Asia, that have allowed them to create efficient and really well-organized vaccination services, and have had

the ability to incorporate new vaccines, some of them very expensive ones, like the ones we use against Rotavirus, which causes diarrhea, or against pneumococcal disease, which causes pneumonia, and infections in the ear, and infections in the brain. So in that sense, now, using that principle, what GAVI did was to make a proposal of expanding that and creating this fund with the money coming in from all different sources, which now has close to $3 billion, to be able then, once the vaccines become available, to make sure that the poorer countries have access to these vaccines without cost, the middle income countries have a way of sharing costs that would also make them cheap, the vaccines, because they're buying huge amounts, and then, of course, having enough supply to be able to make sure that all these different groups have access.

The other part is the humanitarian part. We have a large number of communities that are displaced. We have areas of high conflict. We have the whole problem in Yemen, which is very, very dramatic. And of course, we want to make sure that those countries and those groups of people also have access to these vaccines. In the case of the COVID, one in difference to others, the companies have decided to minimize their cost and have only a replacement of these basic costs without actually making a profit, which is highly laudable them, because this is not the moment to make business, this is a moment to have the world make something different.

And in that sense, what we're waiting now is for all these other vaccines, like you were saying the ones produced in Russia, or in China, to be able to come up with their information so that we can see them in the same way, make sure that they are safe, and then make the same type of recommendations in that sense. Now, we are being overtaken by events. Countries are doing their own bilaterals to buy vaccine because they have a pressure from their communities to immunize them. But in a sense, what we feel is that we are taking care that everybody should have at least a chance to be able to share in this product and not just the countries that have the resources to do it.

Mark Masselli: We're speaking with Dr. Alejandro Cravioto, who is Chair of SAGE, the principal advisory group at the WHO on vaccines and immunizations. You know doctor, it may be not all around the world, but certainly in the United States, we're hearing a lot of people who have sort of vaccine hesitancy. And you add to that hesitancy the emergence of a number of variants to the COVID-19 vaccine. We had the UK variant, the one in South Africa really causing a number of set of problems. And I think WHO just convened a meeting of scientists around the globe to track the COVID variant. Tell us more about it. Should people be worried about it? Or is this sort of a normal Novel Coronavirus mutation that sort of happens all the time? If it's a normal one, could

there be an abnormal one? And how are you tracking all of those?

Dr. Cravioto: I think it's normal for the virus to mutate. And in the case of this one, which had spread so widely, of course, there are many cultures in development. Every person who's infected, it's actually in your culture for the virus, and it has to adapt to a lot of things. One is to adapt to our own genetics. Some of us are resistant to the virus, because our genes have that capacity as we are resistant to the HIV virus, for example. And it's a small group, but it's also something that we know happens. In the case of the of the variants, I think the most important thing of the session, long session, five hours that we had yesterday in WHO to look into this, was to create an international network of people looking at these things at the same time, sharing the strains, sharing the reagents, sharing the information, that would allow us as we have done with Influenza, or we did many years ago with Salmonella, to be able to have a worldwide recognition of what is actually happening.

The other is, of course, looking for these variants and seeing how much they are actually moving in a sense of danger. I think they have to be looked at and they have to be clearly studied to make sure that we are still in a capacity with our drugs and our vaccines to be able to curb them, or if they are really something that we really should see, and control in a different way. So far, all the evidence that we saw yesterday, and the evidence that has been published, doesn't seem to do that. Although the variants are worrying, nobody has actually been able to prove, one, that they are more capable of causing a more severe disease, which is something, one, we really don't know if they're capable of transmitting from one person to another. More often, we have the data from the UK, but that also has other things at the same time happening in the country that mask a bit what is actually happening. And on the other hand, and there's going to be a meeting in WHO on Thursday, tomorrow, is that we want the International Health Regulations to look into this to see if there are any restrictions about travelling or any requirements for travelling.

In that sense I think that everybody's looking at this, and as we have done with the vaccine, it has to be a joint work of every country not putting restrictions just by itself, but actually thinking about how we control this issue. The data we have published so far, only comes about the response of people vaccinated with the Pfizer vaccine, showing that the antisera that they have, the serum taken from these volunteers, or these patients, neutralizes, I mean controls the growth of the variants. So that is good. But they're happening all the time. You have now a new one of people going from Brazil that has a large Japanese community to Japan, and then bringing the virus from Brazil to there. And then I'm sure that if we start studying them, we will see that happening more frequently. So we need to be aware of the

problem and try to handle it in a more coordinated way than has been done so far, when these things have been more isolated in their capacity of being analyzed.

Margaret Flinter: Well Dr. Cravioto, it seems like a very long time ago, January 2020. But I remember we, with great pleasure, launched the World Health Organization International Year of the Nurse and Midwife. And here we are in 2021 and we were so pleased to see that the World Health Organization named 2021 as the International Year of Health and Care Workers in honor of the incredible sacrifice, commitment, heroism of health care workers all over the globe that have treated patients during this deadly pandemic, and really with considerable loss of life in the United States and in other countries. How do you think we're doing at getting the vaccine to the frontline workers in countries all over the globe, as well as the PPE they need to keep themselves safe? Are we making progress there, and is that death toll coming down around the country as we move forward around the globe?

Dr. Cravioto: I think that's an excellent question. First of all, I would say that we're all in the hands of these people, and the only thing we can say is thank you because they are putting their life on the line to be able to keep us safe and treat our relatives and the people who get very sick, and thanks to them, many of them come out alive. The second is that we have had a large number of people dying, and that has been a huge tragedy everywhere that has happened. And I think this just shows why we decided in SAGE in the first document that we produced, that looking at the ethics of how these vaccines should be allocated, the first group that had to be vaccinated are the frontline workers that we call the health workers.

That includes not only the doctors and the nurses, it includes the people who clean the hospitals, who bring the food, who drive the ambulances, who are all exposed to this, the people who take care of the dead, etc. we call the frontline, and those are the ones that we feel should be vaccinated first. I think it's something that we need to do to make sure that we keep our health workforce robust, healthy, and safe in that sense. The problem, as you have seen in the United States and in other countries, is that many health workers are now reluctant to use the vaccine, because there has been this idea that they lose a day at work, that they don't feel very well, that they might have an allergy, and that is something that worries us because they are our best disseminators of saying that the vaccines are good and safe in any part of the system. So if they're not convinced, then who can convince the others?

And so we are trying very hard to create all the necessary elements for them to be assured of the safety of the vaccines, but at the same time to make them good ambassadors in the sense of why we need

this vaccination. And what we need is information and people that can be trusted. And on the other hand, with the social media expanding, as it has, there are too many people saying the most outrageous things against the vaccines that people hear, question and sometimes don't have a good answer back in the sense of saying, look, this is rubbish, and don't believe it. Why? Because of this, this, this, not because I'm the expert that I know more than you, but because there is this evidence that comes up. Offit is one of the great communicators of that, as you probably saw, and he has been working for years in this type of hesitancy problems.

We feel, as part of the recommendations that we gave, that the communications part, especially to the communities, has to be very strong, and we have to make sure that the people get the answers that they need. WHO has created some question and answer pages, which are good. Some of them are in more than one language, which is also very good. The Pan American Health Organization has one in Spanish because of the amount of people living in this part of the world who speak that language. So, in a sense I think we are trying to move into convincing people that that is something. One of the problems with the Pfizer vaccine is these allergies that they can cause in certain people, and has been something that [audio cut 00:23:40]. So we have something in the recommendations about that, But on the other hand, if you have an allergy to a food or to the environment, to dust, that is not a reason not to get the vaccine. This is really allergic reaction, severe ones to either vaccines before, because of some problem, or people who have allergies to something that can put them in real danger of having a severe event. So, in that sense we have that, and at the same time, we have insisted that because of those allergic responses we need to make sure that in the places where the vaccine is given, that we have the treatment for any case happening in that case, and that is – Yes.

Mark Masselli: Dr Cravioto, you know, you have such a great perch, sort of a global view of how the world has come together, at least at the scientific community level, and I'm just wondering, are you hopeful? We know we had SARS and MERS. We've got COVID-19. Are we prepared? Or are there lessons learned from the scientific community of how we manage not only finishing this crisis but be prepared for the next one? And is somebody modeling up if we're not as good as we should be modeling up what the best response might be?

Dr. Cravioto: I really thought that after the SARS scare that we had, that we would be far more prepared for this one. And I'm sorry to say, but that hasn't happened. I think Bill Gates said the same thing long before me, that we have been prepared. With the H1N1 in the US, President Obama created this whole group of a pandemic response, which was really part of the White House, and we had groups all over the world

looking into this. But this time, I feel that again, we were ill prepared, one, to be aware that there was a massive problem coming. And we can blame anybody for that, it doesn't make any difference. We have prophets who said something that is difficult to follow in a sense. And I think what it's clearly shown is that we need to have a much better international understanding of what is happening. This team that has just arrived in China to look into how this whole thing started, it's going to be very important. And I'm very glad that the WHO sent them, and of course, the Chinese government accepted to go through this whole process of understanding where were the delays.

I don't think putting blame is going to help anybody, but we do need to have some kind of lessons learned about this, because this is not the last one. We are in constant contact with these viruses that come up, these viruses that come mostly from animals and jump into humans. And we have had HIV, we have the Ebola, we have this one, and so all of these are the same type of viruses that start in an animal, and then suddenly jump into humans, when they can adapt, and then they spread. How much we controlled the spread, until now, had been more successful, but with this one, I think we were not aware of its capacity really, to infect this huge amount of people.

And on the other hand, the only thing that we seem to have had in hand was to tell people stay home, don't go out, at first. And to be honest, I mean, I was chatting with a friend of mine who lives alone in Bangladesh, and she's desperate, because she hasn't seen her family for a year. She lives there. She doesn't want to go out. She's scared. All these things come up, and there's no solution for her, except now to get a vaccine, that is still not available where she is living. So I think we have to recognize that we need a much better system of control and awareness than we have in place.

The World Health Organization is of course, where we put our money into doing this type of things, but it has to have the response and the leadership from all the governments that are part of the organization to be able to function properly. And there we have had a very mismatched response from one government to the next on how to manage this. What I do think is that now with the vaccines available, if we can control this program, we really need to assess how do we setup a system of awareness and red lights that allow us to be able to be prepared for this. Because it's amazing that we're now going back to the experience of a 100 years ago with the Influenza epidemic in 1918, and now this one, I would say we hadn't learned in a 100 years anything except to wear a mask, or stay at home. Now fortunately, in this case, we have developed vaccines and it's a magic because some of them are really novelty vaccines that are going help not only with this disease but with others. So, in a sense, I think that if we don't take this chance as lessons learned, I think we're going to be having a

very missed opportunity of actually doing something different the next time.

Margaret Flinter: We've been speaking today with Dr. Alejandro Cravioto, the Chair of SAGE at the World Health Organization. Sage is the principal advisory group at the World Health Organization on vaccines and immunization. You can learn more about his work on vaccines by going to who.int/immunization/sage and follow their broader mission by following them on Twitter @WHO. Dr. Cravioto, we want to thank you so much for your efforts, your humanitarian efforts, your scientific efforts, making the world a better place, and for joining us today on Conversations on Health Care.

Dr. Cravioto: Thank you for inviting me, a pleasure to be with you.

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Mark Masselli: At Conversations on Health Care, we want our audience to be truly in the know when it comes to the facts about health care reform and policy. Lori Robertson, is an award-winning journalist, and Managing Editor of FactCheck.org, a nonpartisan, nonprofit consumer advocate for voters that aim to reduce the level of deception in U.S. politics. Lori, what have you got for us this week?

Lori Robertson: Two COVID-19 vaccines are now authorized in the US by the Food and Drug Administration, one vaccine from Pfizer and BioNTech, and another from Moderna. We'll take a look at how these vaccines work. Both the Pfizer BioNTech and Moderna vaccines are mRNA vaccines that require two doses. The vaccines work by triggering an immune response against the spike protein of the SARS CoV2 virus. That spike protein sits on the surface of the Coronavirus and is what the virus uses to enter cells. The vaccines are made of modified messenger RNA or mRNA, wrapped in a special blend of fatty molecules known as lipid nanoparticles. The mRNA provides instructions for cells to make their own spike proteins, prompting the body to generate protective antibodies and activate T cells. The lipids help deliver the RNA into cells and prevent it from being degraded too quickly.

The Pfizer BioNTech vaccine includes 30 micrograms of mRNA in each dose. Moderna shot has 100 micrograms. The two vaccines also use a different mix of lipids. As the Centers for Disease Control and Prevention has explained, there is no way to catch COVID-19 from this type of vaccine because the vaccine is not made of a virus, and because the mRNA from the vaccine doesn't enter the nucleus, the part of the cell that houses DNA, it ‘does not affect or interact with a person's DNA,’ the CDC said, contrary to some online rumors. The Moderna vaccine was developed in collaboration with the National Institutes of Health. Researchers at the National Institute of Allergy and Infectious Diseases Vaccine Research Center were already

working with scientists at Moderna on an investigational vaccine to protect against MERS, another disease caused by a Corona virus.

As soon as the genetic sequence of SARS CoV2 became available in January, the team was able to apply that knowledge to design a COVID-19 vaccine. German company BioNTech designed multiple mRNA vaccine candidates after the genetic sequence of the virus became public in January and partnered with Pfizer in March. According to the results of the Phase III trials, the two vaccines had an efficacy of 94% or higher, which approximately means your risk of getting sick from the Corona virus, is cut by 94% or more if you are vaccinated. And that's my fact check for this week. I'm Lori Robertson, Managing Editor of FactCheck.org.

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Margaret Flinter: FactCheck.org is committed to factual accuracy from the country's major political players, and is a project of the Annenberg Public Policy Center at the University of Pennsylvania. If you have a fact that you'd like checked, email us at chcradio.com. We'll have FactCheck.org's Lori Robertson check it out for you here on Conversations on Health Care.

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Margaret Flinter: Each week Conversations highlights a bright idea about how to make wellness a part of our communities and everyday lives.

Baltimore, Maryland has one of the highest emergency medical call volumes in the country, and it results in a significant number of patients being taken to the ER for conditions that could have been treated outside of the ER. The University of Maryland Medical Center and the Baltimore City Fire Department teamed up in the hopes of reducing unnecessary ambulance trips and hospitalizations. They created a new pilot program, which pairs doctors and nurses at the hospital level with paramedics in the field, bringing medicine right into the patients' homes.

Dr. David Marcozzi 911 low-acuity calls, we augment the Baltimore City EMS system so that we co-dispatch a paramedic and either nurse practitioner or doctor to the scene of low acuity calls, and we then enroll them into our program, we then treat them at scene, discharge them with prescriptions as needed, and then we follow up with them within 24 hours.

Margaret Flinter: Dr. David Marcozzi, of the University of Maryland Medical Center, says that this community paramedicine program has a two-pronged goal, one, reducing unnecessary trips to the ER by delivering right care at the scene, two, bringing a coordinated paramedicine team including doctors and nurses into the homes of patients being

released from the hospital to ensure that their recovery is supported for better outcomes, thus greatly reducing the risk of re-hospitalization.

Dr. David Marcozzi: It's eye-opening too, once you understand the challenges when we discharge a patient, people stay just at home to navigate the insurance industry, the multiple providers they're supposed to follow up with, then the follow up back to their primary care, and we are exploring could we do this for longer. For THS, our data demonstrates that the patients who are followed in our program, are admitted to the hospital significantly less, that translates into lower cost to the system.

Margaret Flinter: But most importantly he says the patient outcomes are markedly improved. The Mobile Integrated Healthcare Community-Paramedicine Program, reducing unnecessary emergency room trips, now that's a bright idea.

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Mark Masselli: You've been listening to Conversations on Health Care. I'm Mark Masselli.

Margaret Flinter: And I'm Margaret Flinter.

Mark Masselli: Peace and Health.

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Marianne O'Hare: Conversations on Health Care is recorded at WESU at Wesleyan University, streaming live at www.chcradio.com, iTunes, or wherever you listen to podcasts. If you have comments, please email us at www.chcradio@chc1.com, or find us on Facebook, or Twitter. We love hearing from you. This show is brought to you by the Community Health Center.

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