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Exploring the Ethics of Vaccines

Announcer:
Coming to you from the ReachMD studios, this is *COVID-19: On the Frontlines*. On this program, ReachMD host Dr. John Russell will share some ethical considerations for vaccinations, especially amid the COVID-19 pandemic.

Here's Dr. Russell now.

Dr. Russell:
Hi, I'm John Russell, so thank you for joining me today. I'd like to talk a little bit about ethics of the COVID vaccine. Certainly, this is something in the news, and certainly there are lots of questions. As always, I think it really helps to think about these things certainly in an ethical framework with regard to medicine, and I think we also need to think about, you know, where we've been over the years with regard to vaccines, how we got to where we are now. So some of the objectives I'm gonna talk about is how issues of beneficence and nonmaleficence apply to the manufacturers of vaccines; they are two concepts we talk a lot in medical ethics, and I'm gonna talk about the role of justice in a society's allocation of a scarce medical resource like a vaccine, talk about informed medical consent, and talk about patient autonomy on the application of vaccines in health care.

So there are four main pillars in American medical ethics – autonomy, beneficence, nonmaleficence and justice – I'm gonna talk about each one individually, as we go through that. But really, if you look in the United States in 2020, these squares are not all the same size, and certainly autonomy is king. So certainly in the United States, we allow competent adults to make whatever decision they want for themselves, as long as it does not hurt someone else. And we'll kinda talk about how we got there. So some of the ethical issues are safety and efficacy of vaccine production, who is it ethical to test vaccines on, how to respond to safety issues that may arise, how to decide how to distribute the vaccine, making vaccination mandatory, and how does society deal with a vaccinated versus an unvaccinated population.

So certainly, I'd love to look back so we can look forward, and some of the people, I think, that are some of my heroes in the area of vaccines started out with doing some things that I'm not sure in today's light, we would feel great about. So the father of modern vaccinology would be Edward Jenner, a physician in the late 1700s in England. He noticed that milkmaids who got cowpox did not get smallpox, so he took some cowpox material, injected it into the son of his gardener, and then a few weeks later, exposed him to smallpox, and found out that he, indeed, did not get smallpox, and that started vaccination – vacca for cow. But certainly, I would think that someone who's testing something that's never been tested in humans before, testing it on an employee's child would not be something that we would look upon to ethically in today's day and age.

History of vaccine law – so an interesting thing is, since the 1850s, Massachusetts was the first state to have laws that made it mandatory for children to be vaccinated. Germany, in the late 1800s in some of the parts of their kingdom, made vaccination mandatory, in other parts it wasn't. The difference with regard to smallpox mortality was 30-50 times higher in the areas where there was not mandatory vaccinations. And if you look up in the corner of the United States, we only have four states that actually do not allow people to have some religious exemption: California, New York, West Virginia, and Mississippi. New York was the most recent one to add that. Pennsylvania – my state –allows both personal and medical exemptions for people not to be vaccinated, which personally, I think is problematic. Louis Pasteur, another one of my heroes – Louis Pasteur was not a physician. He was working on coming up with a rabies vaccine. There was a nine-year-old boy who was bitten by a rabid dog. His mother brought the child to Pasteur to help. He gave him 13 doses of his experimental rabies vaccine. He was the first person to get a full course of treatment. He did not succumb to rabies. Rabies is pretty much 100% fatal, even now, without treatment, and this young man lived. He never developed rabies. In fact, he worked the rest of his life for the Pasteur Institute. Again, you know, how would we feel about someone testing something on a child, someone

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who wasn't a physician – so Pasteur was was a scientist, but was not necessarily a physician – I think we might all agree that this was a dire strait, that this child would have otherwise died, but again, you know, I don't how ethical we would feel about that.

Polio was the scourge of the 20th century. Franklin Roosevelt developed polio in the late 1920s. Koprowski was the first one to work on an oral polio vaccine, and to his credit, he and his assistant were the first ones to take the oral polio vaccine. He worked for Lederle Labs at the time. Sadly, Koprowski then went on to test his vaccine on disabled children in some institutions in New York. Jonas Salk, one of my personal heroes, he tested the vaccine in homes for disabled children as well. He went on to vaccinate his wife, himself and his family and there's a picture of his son, Peter, being vaccinated very early on, but he still did some testing on a vulnerable population, that I'm not sure we would embrace in this day and age.

If we're gonna have a vaccine, we want it to work. And most vaccines go through years and years of safety and efficacy standards. Now, people are like, "Boy, they've certainly kinda rushed through this." And certainly, a 10-month window is pretty remarkable for coming up with a vaccine. Some of the shortest vaccines that we've seen come into development have been about four years. But it also goes to show if you throw a billion dollars at a company involved in science, a lot of stuff can happen a lot more quickly, and science is probably moving at an ever-faster pace.

So the research process involves diverse scientific social disciplines, epidemiology, public health, immunology, and the companies who make it, and all of these people weigh in with different priorities as vaccines become developed. I have a Hippocratic oath on the wall of my office here, and it says, "I will prescribe regimens for the good of my patients according to my ability and my judgment, and never do harm to anyone, and I will give no deadly medicine to anyone if asked, nor suggest any counsel." So the general ethical principles with vaccines – so first is beneficence. So in medicine, we should be trying to do what is right, what is good.

Now, prior to World War II, this was the main construct in medical ethics in the United States. Doctors kinda taking it up themselves to decide what's right, and that extreme is really paternalism. And, you know, once upon a time, and even in some countries, people might not be told what their diagnosis is. So that really is beneficence, probably taken to an obscene, probably unethical, standpoint. And nonmaleficence – I shouldn't do something that is harmful. I should not do something that is not in the best benefit of society. So the frame – you know, "first do no harm – primum non nocere," from Latin is one of the things we learn very early on in medicine, and we should be making decisions in the overall kinda best view of society.

So safety issues in vaccines – so, as I said, Jonas Salk, one of my heroes, came up with the polio vaccine. When Edward R. Murrow asked him if he was going to patent it, he said, "Would you patent the sun?" So, he had a recipe, how to make vaccines, and then manufacturers around the country started making polio vaccines, and there was an incident in 1955, by Cutter Labs in San Francisco. They were supposed to be inactivating the polio virus. They did not in a bunch of their vaccine, and there were 250 cases of polio attributed to vaccine in this one country – the Cutter incident. And, you know, I'm not completely sure if this happened today, if this would not be something that would grind something completely to a halt, but polio was such a scourge at that point, that, you know, people corrected this, and a lot of the vaccine commissioned to deal with injuries was created because of this.

1976 – we were worried that there was a new strain of swine flu that would be very reminiscent of 1918-1919. There was a recommendation at that time to vaccinate everyone. And yes, we live in a time in 2020 that we should be vaccinating everyone over six months of age against flu, but this was something that was new, against this novel flu vaccine. Here's a picture of Gerald Ford getting his swine flu vaccine. That season, and that season only, there was an increased rate of Guillain-Barre syndrome, associated with the flu vaccine. So, there were roughly 400 cases of Guillain-Barre syndrome, which is a neurologic condition with a little bit of a. ascending paralysis, which can happen with cases of the flu. A patient I take care of, who won't get a flu shot every year, who got influenza and got Guillain-Barre syndrome from the flu itself, not necessarily from the vaccine. So the Institute of Medicine looked at a thorough investigation of all the vaccines besides that particular year and really did not find an increased incidence beyond that 1976 year.

The dengue vaccine – so, dengue fever is a mosquito-borne illness that affects folks worldwide – 3.2 million cases, 9,000 deaths – the first infection people often get with dengue fever is rarely fatal. A recurrence often can be. So a vaccine was developed in 2015, recommended for folks over nine years of age, and recommended in endemic countries. And after it was released, researchers found it protects about 80% of those who got it, and if you look over here, this is for people who've had dengue before – who were previously exposed. It's a good vaccine. For people who hadn't had it before, it increases the risk, so that mild first case of dengue can actually be something serious. They gave it to 830,000 folks in the Philippines. There were 130,000 deaths related to that.

So, one of the ethical questions is the trolley question. So the trolley ethical quandary is if I'm upstream from a trolley that has careened past me, and it's gonna hit five people on the track, and I can flick a switch to move it onto another track, but it would kill one person, should I do that? And, you know, the difference to think about is if I do nothing, I mean I didn't put the trolley on that track that's gonna hit the five people, five people are gonna die by fate. If I flip the switch, I will save five lives, but I will kill one person who will really die by a

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decision that I made. So that's that trolley ethical quandary that we often have, and who's that one person? You know, does it matter who that one person is versus who those five folks are? And certainly, I think as we start to look at things like self-driving cars, I want my self-driving car protected that I would rather something happen to me as a passenger if the car is gonna careen into a crowd of people. So I think these are ethical decisions we will see in lots of things in our life.

So who protects the rights of a recipient? So there's been a vaccine injury program since the 1980s. So in the 1980s, a lot of the vaccine companies were just gonna go out of business. They were lawsuits, and the companies were gonna go out of business, so they put together a vaccine injury compensation program. So basically, for every vaccine that is given in the United States, X number of dollars are thrown into a kitty to help compensate people who might be injured by a vaccine.

So talking about the polio vaccine, there was a live polio vaccine. The oral polio, that we might have gotten on sugar cubes, that was developed by Sabin, this live oral polio – one in 500,000 people who got that, got polio from that live vaccine. So if roughly we were giving the vaccine to four million children a year, there were about eight cases of polio related to the vaccine. And that was a known thing, and that was kinda the risk that our society took in our trolley equation. And certainly if someone was injured, there was some money to help compensate, you know, help try to make whole as best they could, that person who was injured. And actually, if someone is injured by a vaccine in the United States, it doesn't go to a regular court. It goes to a vaccine court. So there is a vaccine court that has special attorneys, special judges, special people who argue before this case, to kind of figure out if something related to a vaccine or not, and that's really how vaccine cases area adjudicated in the United States, and that's how people are compensated.

So, informed consent – very important in medical ethics, if we're going to do something for someone. Was someone given all of the information up front, to know what are the risks and benefits of doing something? Vaccines are a little bit different, so federal guidelines do not require written consent before vaccinations as they do with procedures. You're having your appendix out – someone should give you some written information for informed consent that you would sign. The National Child Injury Act of 1986 requires that doctors give vaccine recipients, or parents or legal representatives, a vaccine information sheet. So this sheet should be given any time he gets a vaccine, and that's partly part of participating in this program.

And then the testing of vaccine, and who should the vaccine be tested? So we really want vaccines tested on populations that will reflect who would get the vaccine. So certainly, we wouldn't want childhood vaccines tested on middle-aged adults. And maybe they would do some tests early on on some middle-aged adults for safety, but for the most part, we want to test things in the population that's going to receive this. The Helsinki Declaration states that research within a vulnerable group is only justified if the group is responsive to the health needs and the priorities of this group.

But again, looking back, testing of vaccines on inmates. 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research instituted a moratorium on research in correctional settings. For years, there were things that were happening in prisons with regard to the testing of drugs, testing of vaccines, even in the World War II era, they were giving inmates malaria to see if that would treat syphilis, as an example. So certainly, things have happened kinda over the years, and sometimes people got a couple dollars for doing it, but just doesn't seem to be ethical. In 2006, the Institute of Medicine suggested updates to improve the ability of incarcerated individuals to participate in limited clinical studies, particularly those with minimal risk and interventions, with demonstrated safety and efficacy. So there are things that happened in prisons. COVID certainly happened more commonly in people who were in prison versus people who were free. So it might have been a very great population to test it in. But the question is, do people really have liberty to say "No?" And then studies in institutionalized children – you know, sadly there's a Willowbrook State School, in Staten Island, New York, that there was a 14-year study beginning in 1956, that they infected disabled children with hepatitis to see how gamma globulin would work in protecting them, and certainly this is stuff we never wanna see happening again.

And then distribution of the vaccine. So the ACIP has certainly hammered out who should be getting the vaccine first, and certainly they are looking at people who have high-risk medical conditions, essential workers, in which health care workers are 20 million of, and then adults, 65 years or older. So certainly it's been diagramed, but we're in the 150s of millions of folks who would be in that Phase 1. The ACIP last week actually said, "These are the folks who should get the vaccine first," would be health care workers, paid or unpaid, who have potential for direct or indirect exposure to COVID, and then folks in long-term care facilities. So how do we decide, as a society, who gets a scarce resource, and the medical ethics concept is justice. And, you know, justice is the one that we deal with least in medical ethics, because we don't tend to have a limited number of bypass surgeries available or colon surgeries available, or hysterectomies available, or anything like that. We seem to have a limitless resource. Justice comes into when we talk about organs, right? We only have so many kidneys to distribute, so many livers, so many hearts, so justice falls into that.

Certainly early on in the COVID pandemic, we were thinking about, as a society, if we don't have enough ventilators, how will we allocate this scarce resource that we can't get more of. And justice would be the concept of this. So the principle of justice states that

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there should be an element of fairness in all medical conditions, fairness in the decisions of burden and benefit as well as equal distribution of scarce resources and new treatments for medical practitioners to uphold laws, and legislation.

And then access – you know, many of the debates really focus on socioeconomic issues, so certainly COVID has been a disease that has affected certain disenfranchised populations in the United States much more than other populations. And if a vaccine becomes available, you know, will it just go to the wealthy? Will it just go to the people who have a certain amount of cache, or will it be distributed equally amongst the population? And, you know, we think about economic things, and the vaccine is not going to cost money for people in this initial thing, but just remember, 10% of our essential workers have no health insurance. So, not only have these people been very heroically going to work each day keeping the country supported, but a lot of them don't have health insurance if they get sick, which is, you know, very tragic. Zeke Emanuel, who works at the University of Pennsylvania as an ethicist, kind of talked about some of the phases of fair vaccine distribution. We should try to reduce premature deaths and priorities to countries where the standard expected years of life lost would be greatest. We want to reduce serious economic and social deprivations and work to more companies that are losing more of their gross national income based on COVID, and then returning to full functions, countries with higher transmission rates. And sadly, as I talk in December of 2020, that's the United States.

Mandatory vaccinations of health care workers – so this is certainly something that everyone is talking about, and very passionate about, one way or the other, and the question is the balance of autonomy, right? We said that that is king. Someone making decisions for themselves, versus my responsibility to others. So, patient autonomy and informed consent – who can give informed consent? Well, to give informed consent, I need liberty – so I need to be free to say yes or no. I can't force my employees to have to say, "Yes, I wanna participate in this trial." You know, prisoners would be perfect example of folks who don't have liberty to do that, forcing students in a university to have to participate in something that might not be ethical. And then, do I have agency? Do I understand what's going on? Do I have capacity to make that decision and understand the ramifications of my decisions? A lot of this autonomy being king dates back to a lot of the Nazi atrocities that happened during World War II, at the hands of physicians who did things that weren't ethical, that patients did not elect to participate in. The big Supreme Court case was Canterbury vs. Spence in '72, where someone got paralyzed with a back surgery and was not informed that that was part of the risk of actually having a back surgery done. Emanuel Kant is one of the kind of fathers of ethics, a German philosopher from the late 1700s – kind of an idealist, and talks about our responsibility to others. And the categorical or unconditional imperative has practical applications for the study of ethics. So we should act on the basis of goodwill, rather than purely on self-interested motives that benefit ourselves at the expense of others. And we must never treat ourselves as means towards benefiting ourselves, without consideration of ends in themselves. Kant held that absorbing the categorical imperative would rise all boats, and would make ethical actions happen on our part.

There was a lawsuit with regard to mandatory vaccination, in Cambridge Massachusetts in 1905. There was a law that everyone had to be vaccinated against smallpox. A man named Jacobson refused to get vaccinated. He was fined five dollars, traveled all the way up to the Supreme Court, and the question was, "Does mandatory vaccination law violate Jacobson's 14th amendment right to liberty?" The Supreme Court held that the law was a legitimate exercise of the state's police power to protect public health and the safety of its citizens. Local boards of health were the ones who were determining when mandatory vaccinations were needed, so that requirement was felt to be neither unreasonable nor arbitrarily imposed. And this was from the National Law Review from this month – can employers mandate employees to take COVID-19? My institution will not be making it mandatory, nor do I view any institution making it mandatory. It still has emergency use authorization, and it'll probably be two years till it's through all the kind of the FDA requirements, but it's certainly kind of worth discussing.

So, disability impact –people can be felt by the Equal Employment Opportunity Commission that a person could be exempt if it impacts their disability, and the Americans Disability Act would trump that mandatory requirement for a vaccination. Religious accommodations – so if someone had certain religious accommodations and receiving the vaccine could be proved a hardship, the same Employment Commission felt that that could override someone's mandatory need to get a vaccine, and then can you make workplace accommodations? So, I work in an institution that it is mandatory that you get the flu vaccine. And over 1,100 hospitals in the United States have that as a requirement. There are other hospitals that say if you do not get a flu vaccine, you have to wear a mask from November to March. Now we're all wearing masks right now, and certainly even if someone got vaccinated with the COVID vaccine when that becomes available, it certainly will not relieve us of having to wear masks and face shields and all of the stuff going forward. But the EEOC also does understand that a pandemic is different, so we are not vaccinating someone against a rare disease that is in some distant land, that really doesn't have a chance of sitting at your Christmas table. Certainly, the threat of COVID kinda walking in any of our front doors is real. And certainly, this is something that the country is on fire again with.

So, Supreme Court Justice Oliver Wendell Holmes said – talking about harm, and the right to swing my fists ends where other man's nose begins. Certainly I think this really is a little bit of the concept of people not wearing masks. You know, you have a right to wear a mask, you don't have a right to not wear a mask. You don't have a right to infect me. And that's really where that question of harm. And

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then the ethics of society on immune status, which I think is very, very interesting, and this might be kinda what we're dealing with afterwards. So if you looked at New Orleans in the late 1800s, they had gone through 22 epidemics of smallpox, excuse me, yellow fever. And about 10% of the population had gotten yellow fever every year. If you had moved there from the north, you couldn't get a job, you couldn't get a place to live, you couldn't find someone to marry, until you had been acclimated, until you had had yellow fever. It was really considered a baptism of citizenship. So certainly the United King's Health Ministers proposed immunity certificates, wrist bands. They've talked about it in Germany and certainly Anthony Fauci has talked about this as well. Around Thanksgiving, Qantas Airlines out of Australia became the first airline to require passengers to get COVID-19 vaccine before flying internationally.

So, private companies can do what they wish, and you could imagine that there would be a lot of things that if you had been vaccinated, that you could suddenly do something, and your mind is kind of limitless to say, you know, something that is rarified could they have exclusive concert to see a certain artist in a small venue, but everyone had to be vaccinated. Could the most elite restaurants suddenly require everyone to be vaccinated? And I think we are going to see that. Well, is that ethical? Can you do that? Well, certainly yellow fever – there are countries on the planet that yellow fever is still endemic. You cannot enter this country unless you've been vaccinated against yellow fever. You cannot enter other countries from these countries, unless you've been vaccinated against yellow fever, to decrease the spread. So certainly there is precedence – we are dealing with going through the vaccine life cycle, and Phase 1 is that trial early on, on people just really looking at safety, looking at under 100 people. Phase 2 is you're starting to look at effectiveness, immunity, and then Phase 3 are the trials that we are hearing back from at this point. So certainly, this was from early November, but the coronavirus vaccine tracker is in the New York Times – you could follow this to see where the status of vaccines. About 60 vaccines are working their way towards market. The two vaccines that we're probably gonna be receiving, you know, the Pfizer vaccine was recently FDA-approved for that emergency use authorization, and we're gonna start to do this. They are both mRNA vaccines. mRNA vaccines is really the recipe. The mRNA to make the spike protein, that kind of protein on the end that makes up the crown is put in some lipid coating molecules that get into cells. This recipe get its into the protein-producing ribosome, in the cell that makes these spike proteins. You're not giving someone the whole virus. Someone cannot get COVID from this. You are giving the recipe to make the spike proteins. And these illustrations are from National Geographic, and then the antigen presenting cells in the body make antibodies against these spike protein cells. And all of the vaccines that we are looking at, for the most part, are some variation on this, as getting the body to make antibodies against spike proteins, and then if you look, you can block these spike proteins with antibodies, and that will prevent them from attaching to the cell and reproducing. Remember, viruses themselves are not necessarily alive – they require cells for reproduction.

So hopefully this helped you all understand a little bit of where we've been overall. Vaccine will be coming available very soon, as a physician who works in the hospital, I will probably be receiving it fairly shortly from my institution. I definitely will be getting it, and I'll kinda be sharing my experience. But I think it's a great thing, and hopefully this helped clarify some issues with folks with regard to this. But, I think the vaccine is a little bit of our kinda best answer without kinda burning through, you know, another 500,000 million people dying, with getting herd immunity. So, thanks for listening. I hope this was worthwhile.

Announcer:
You just heard the latest on the ethics of vaccinations from Dr. John Russell. To access more episodes from *COVID-19: On the Frontlines*, and to add *your* perspectives toward the fight against this global pandemic, visit us at ReachMD.com and become Part of the Knowledge. Thank you for listening.

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