

Transcript for program “**CDC Responds: An Update on Treatment Options for Postal and Other Workers Exposed to Anthrax,**” videotaped on Thursday, December 27, 2001, at the Centers for Disease Control and Prevention, Atlanta.

Dr. James M. Hughes:

Hello. I'm Dr. Jim Hughes, Director of the National Center for Infectious Diseases at CDC. It's my pleasure to welcome you to the next program in the clinical education series "CDC Responds." As you know, during the past three months, the nation has experienced an unprecedented biological attack involving dissemination of *Bacillus anthracis* organisms through the U.S. postal system. This event has placed a number of individuals at risk for infection, and many people have been advised to take antibiotics prophylactically to reduce their infection risk. As we've learned more about the risk of transmission of *Bacillus anthracis*, we have elected to provide individuals currently taking antibiotics with two additional options to further reduce their risk of infection. Today we will review those additional options with you and to answer some of the questions that you may have related to your personal risk and the options that may be most applicable for you.

It's my pleasure to introduce Dr. Julie Gerberding, who is the Acting Deputy Director of the National Center for Infectious Diseases, who will clarify these options and address some of the questions that you may have.

Dr. Julie I. Gerberding:

Thank you, Dr. Hughes. This episode of "CDC Responds" is meant to target the workers: the people who've been taking antibiotics for the past 60 days and still have questions about what options are available for them next. Now, the workers involved in this situation have many jobs. Some of you are involved in delivering the mail, some of you are in the business of responding to the media, and some of you support senators in the U.S. Capital.

We at CDC are in the prevention business, and what we're interested in is providing you with the information that you need to make good decisions about how to prevent inhalation anthrax. We make prevention messages that many of you are familiar with, such as, "wear a seat belt," "don't drink and drive," "get your children vaccinated." Those kinds of prevention messages are messages that we can make with authority and be very directive because we have the evidence and the common sense to know that those things really make sense for you. But in the situation of preventing inhalation anthrax, we don't have all the information, and we have to rely on the best data we have to give you options for prevention without giving you very specific, concrete advice. So let's go over some of those options.

One important framework for understanding these choices is to remember that over 10,000 people have taken antibiotics to prevent inhalational anthrax, and so far, we have no cases amongst any of those people. So we know that the preventive therapy so far has worked very well. But the question that we're still asking ourselves is, "Have we done everything that we can do to protect people?" There are some people that we're still worried about. Those are the people who've had the highest risk exposure and the people who have had the most trouble taking their full 60 days of

antibiotics. So some of the options I'm going to be presenting are primarily addressed for people who answer "Yes" to either of these two questions:

- Were you working in an environment where there was an especially high dose of exposure, such as the Brentwood or Hamilton postal facilities, the AMI building, or the Senate office building?
- Or were you really having trouble taking all 60 days of your antibiotics, and did you miss many doses, or did you stop early?

If you answered "Yes" to either of those questions, then it would be important for you to listen carefully and think about what other options for prevention make sense for you.

The first option that we have is to take additional days of antibiotics. We've looked at the information from the experiments that are available to us. We've consulted with experts at the Food and Drug Administration, the National Institutes of Health, and many scientists from around the country, and those experts have advised us that perhaps up to 40 more days of antibiotics, in addition to the first 60 days, might be helpful in preventing inhalation anthrax. This is designed to make sure that any of the remaining spores are killed and that there's no late development of infection.

The other option is to use an investigational vaccine -- the anthrax vaccine. Now, using this vaccine requires three shots over a one-month period of time, and it also involves 40 days of antibiotics. There's been a lot of confusion about why people can't just take the vaccine and avoid the extra days of antibiotics. The reason for that is that you need to have the antibiotics onboard while the vaccine is taking effect. So when you get your first dose of vaccine, you don't really have much protection. After the second dose, your protection level goes up a little bit, but you still need the antibiotics to make sure that you're covered. It's not until after the third dose of vaccine that we can be confident that the protective levels are high enough to last. A few days after that third dose, it's okay to stop the antibiotics because now the vaccine itself will be giving you the protection.

So, once again, the two options in addition to the 60 days of antibiotics are:

- To take 40 more days of antibiotics, or
- To take vaccine plus 40 days of antibiotics while the vaccine is taking an effect.

Now, let's talk a little bit about what we can say to help individuals make decisions for themselves in these environments. I've talked about the risk, and I've talked about your capacity to take antibiotics, but I think there are some other things that people think about when they're making these choices.

First of all, how do you really feel about getting shots? Some people really don't like to receive shots, and for those people, getting a vaccine might not be the best choice.

Another consideration is, how much trouble did you really have with the antibiotics the last time around? If you found that they were really interfering with your life or they were so unpleasant that you weren't able to take them very regularly at all, then maybe the antibiotics aren't the solution for you. And if you're in a situation where your risk is not very high, probably you would choose to not do anything else --- just stick to the 60 days you took in the first place and recognize that so

far, we know that's a very safe option for the vast majority of people who have been involved in these situations.

Now, one of the problems that's come up in the context of trying to make these options available to people is that it's the holiday season. And the postal service has asked us not to deliver the vaccine or the next regimen of antibiotics until after the holidays. Some people finished their 60 days of antibiotics before that point in time. And while it's not an emergency to get started on any new treatment, it seemed like it was a good idea to at least allow some extra days of antibiotics to get through the holiday period so that people wouldn't have to be preoccupied with making this decision at that busy time of year. So some people are taking what we're calling "bridge" antibiotics, or extra days of antibiotics, before they're really making the choice to participate in either the vaccine or the extra 40-day treatment option. So the bridge antibiotics are a kind of a stopgap measure. If this had happened at any other time of the year, we probably wouldn't be in a situation where that was necessary. But, unfortunately, here we are in the holiday season, and that was the decision that we made to try to help everybody get through this with the least amount of confusion and disruption.

What this really means in practice is that some people will finish their 60 days of antibiotics, and then they'll take a few more days while they are thinking about whether they want to commit to the longer-term course of either the vaccine or the vaccine plus antibiotic treatment. Let's say you decide that you want to take 40 more days of antibiotics. If you've taken 60 days and then 10 days of bridge antibiotics, then don't you really just need 30 more days of antibiotics when you enter the program? Well, that would make sense, but, unfortunately, that's not the way this program works. And let me try to explain to you why.

The reason for that is that the Food and Drug Administration has very specific rules about how we can use antibiotics. We have permission, or approval, from the FDA to use 60 days of antibiotics for post-exposure prevention of inhalational anthrax. And that's why, when we first made recommendations for treatment, we were comfortable saying everybody should take 60 days of antibiotics if an exposure has occurred. But the Food and Drug Administration has not approved more than 60 days of treatment for this particular problem. So any time somebody commits to a longer-term course of antibiotics, there's sort of an investigational component to it.

So, in the program that CDC is offering, the 40 extra days of antibiotics is really an investigational program. And when we wrote the program, we wrote it for 40 days because that's the advice we received. So, once you make the decision to go into the program for the longer-term, you really are committing to 40 days. Now, of course, you may choose not to take all 40 days. We wouldn't advise that, but some people may decide for themselves that they really don't want to take more than 100 days of antibiotics.

The program itself does ask you to commit to taking a 40-day regimen beginning the day you enroll because that's what the FDA rules require. Likewise for the vaccine, if you've taken 60 days of antibiotics, and you're not ready or you can't make the decision about accepting the vaccine, then you can take a few extra days of antibiotics while those decisions are being made and the system is set up for you to receive your vaccine. Once you decide, "Yes, I think the vaccine and the extra

antibiotics are the right choice for me," the clock starts all over again. Then you begin with the 40 days of the protocol antibiotics plus the three vaccine doses.

I know this sounds very confusing, and I don't expect everyone to be able to keep these days and numbers straight right from the beginning. And CDC and others will be there to help you make sense of it and get the formula written down for yourself.

I think the take-home message is that these extra treatment options are not for everybody. We don't have any guarantee that they're going to make your risk any lower than it already is. But, again, if you were in an exposure environment where you might have inhaled a lot of spores and you had trouble taking your antibiotics, then the additional treatment options may something you really do want to consider.

We have some information about the safety of the vaccine, and that information has been available to you and will be available to your clinician. I think it's very important to recognize that while we call this "investigational," it doesn't mean that we have no experience with it whatsoever. This is the same vaccine that was licensed by the FDA for prevention of anthrax in soldiers. The reason we call it "investigational" in this context is we haven't used it after exposure to prevent infection. Therefore, it's investigational because it's not licensed for this particular use. But the information about the safety of the vaccine for the soldiers who took it really does help us predict what the risk might be after an exposure has already occurred, at least for populations of people who are similar in health status and characteristics to the military personnel.

We do have some concerns about very young people or older people or people with underlying medical conditions, so we will certainly want to make sure that everybody who's participating in the program is monitored and encouraged to report at the very earliest time any adverse events that they experience.

So, we have the program. We have people on-site in the various locations across the United States who are working with workers to try to understand what are the best options in an individual situation. We believe at CDC that as much as we would like to be able to say, "You all should do this," or "You all should do that," we simply can't be that directive. We also believe that people need three things to make good health choices:

- they need information,
- they need access to expert clinicians and support systems, and
- they need some time.

Hopefully, you've had a little time. We're trying to give you information. And CDC is working with employers and state and local health departments to make sure that you have access to clinical experts who can guide your individual decision.

I'm sure we're going to get through this. It's going to take all of us working together to share this information, but we do commit to doing our very best to helping all of you get a choice that works for you.

And with that, let me just say that CDC wishes all of you a happy and very safe new year, and we look forward to answering your questions again in the future. Thank you.