

Yale CANCER CENTER *answers*

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Clinical Trials for Smoking Cessation

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Welcome to Yale Cancer Center Answers with your hosts doctors Francine Foss, Anees Chagpar and Steven Gore. Dr. Foss is a Professor of Medicine in the Section of Medical Oncology at Yale Cancer Center. Dr. Chagpar is Associate Professor of Surgical Oncology and Director of the Breast Center at Smilow Cancer Hospital. Dr. Gore is director of hematological malignancies at Smilow. Yale Cancer Center Answers features weekly conversations about the research, diagnosis and treatment of cancer and if you would like to join the conversation, you can submit questions and comments to canceranswers@yale.edu or you can leave a voicemail message at 888-234-4YCC. This week you will hear a conversation about smoking cessation with Dr. Steven Bernstein. Dr. Bernstein is Professor of Emergency Medicine at Yale School of Medicine. Here is Dr. Anees Chagpar.

Chagpar Usually on this show our guests are oncologists or scientists. You are an emergency room doctor, tell us how that plays in with cancer?

Bernstein This sounds kind of strange at first I admit that. It really reflects my own path in my career. I started training in internal medicine and in fact, I was studying medical oncology and became interested in tobacco related diseases at that time obviously because so many cancers are caused by smoking, but for a number of reasons I decided to train in emergency medicine almost 30 years ago now and when I went into the emergency room I started to see the same kinds of diseases I was seeing as an oncologist and as an internal medicine doctor, people with emphysema, lung cancer, heart disease, and a lot of these things of course were caused by smoking or made worse by smoking. I saw that we were not doing anything about it and I thought there was a real need there and an opportunity for me to try to do something good for our patients in the emergency department. That was really the origin of my interest in tobacco illness in emergency rooms.

Chagpar And certainly tobacco plays a huge role in cancers. Tell us a little bit more about why people smoke? I think a lot of it is sometimes you just try it and you get addicted, but is there more to the story?

Bernstein There is. It is really a combination of things. Some people are predisposed to smoke. We know there are certain genes that predispose people to nicotine addiction just as there are certain genes that predispose people to being addicted to alcohol or other kinds of drugs. Smoking tends to run in families, but we also know that there are important environmental influences, if you grow up around or near people who smoke you are more likely to do it. Then there are certain kinds of behavioral disorders, psychiatric disorders like depression and schizophrenia where smoking seems to help these people in some way, help them cope with their mental illnesses. So there are a host of factors as to why folks smoke.

Chagpar That is another thing that is really common when we talk about cancer. We talk about genes and we talk about family history and we talk about screening for these genes and talking to patients about family history in order to try to understand their risk for developing cancer, is the same sort of thing available for smoking, are there genes that we know of that we can send patients for a panel testing and understand that they are predisposed to smoke?

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- Bernstein Yes and no, there are a number of genes that we know now predisposed people to smoke. They are not really ready for primetime yet in terms of routine care, you cannot go to your doctor and ask for the predisposition to smoking panel, that will probably happen at some point in the next few years. But we are learning a lot more about the genetics of smoking, the genetics of nicotine addiction and even the genetics of understanding how people metabolize the medicines we use to treat smoking. So that it may be possible at some point to design a program of treatment tailored for an individual based on his or her genetic profile.
- Chagpar So that sounds like personalized medicine just like we talk about in cancer therapies where we know that the cancer has a certain genetic profile and then we target those genes. So you are talking about doing the same sort of thing for smoking?
- Bernstein Exactly, yes.
- Chagpar And when do you think that is going to happen? If it is not ready for primetime now, is this a 2-year or 5-year, 10-year kind of thing?
- Bernstein Well, I am not very good at crystal ball stuff, but I am going to guess 5 to 10 years. There is still a good bit of work to be done, but there are lots of other treatments that we have available too.
- Chagpar Let's talk about that because as you know smoking certainly is, as you said, at the top of the shelf, a really important factor that predisposes to all kinds of illnesses. It predisposes to cancer which certainly we are very interested in here on Yale Cancer Center Answers, but certainly also one of the preeminent killers of Americans in this country with heart disease and emphysema and COPD and so on. How do we treat people who smoke? It is just a terrible addiction, what can we do now, what is in our armamentarium?
- Bernstein We have a lot in our armamentarium. There are really a number of ways to attack the problem. The first thing we can do is help prevent young people from starting smoking. Prevention is really in many ways ideal, but if somebody becomes a confirmed smoker we have a lot of treatments. The two general kinds of treatments are medicines and counseling. There are seven different medicines approved by the FDA to treat tobacco use and there are a number of different counseling styles that work as well, both individual counseling, group counseling, internet based counseling and telephone quitline based counseling. All these things work and when we use them together they work even better.
- Chagpar How do the people know, and how do doctors know what treatments are best for an individual? With seven medicines, I do not know that our audience and certainly I did not realize that there were that many options available. Do you kind of just go stepwise, try one thing, if it does not work, try the next thing?

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Bernstein Partly, as I said the medicines, we call it seven but truth be told maybe it is 3 because 5 of them are different kinds of nicotine products. The nicotine is the only addictive compound in tobacco smoke, that is what gets you hooked. Nicotine does not cause cancer by the way, there are many other things in tobacco smoke that do, but nicotine is not one of them. The nicotine gets you hooked. So, we have five different ways to deliver pure nicotine to people, patch, gum, lozenge, nasal spray and an inhaler and then we have two other medicines also, Chantix and bupropion, or Zyban, and all of these can work. So the doctor needs to sit down with the patient and review his or her preferences and come up with an appropriate course of action. Often times a good way to start would be a nicotine patch which is a long acting medicine combined with a short acting medicine like nicotine gum or spray. So if the patient gets a craving at some point during the day he or she can pop a piece of gum in their mouth and feel better.

Chagpar That is interesting, and I think the other point that you made which is an important one is that nicotine is not what causes cancer. Nicotine is what gets you hooked. So getting a different form of nicotine can take away some of the carcinogenic properties of smoking.

Bernstein Absolutely, there is no question that using a pure nicotine in the form of an FDA approved drug is an absolutely safe thing to do. These are about the safest medicines out there. In fact, they are so safe that a number of them are available over-the-counter such as the patch, gum and lozenge and you do not even need a prescription for those. You do not get any of the cancer causing compounds that you find in cigarette smoke. You do not get any of the heavy metals. You do not get the ammonia, you do not get any of the other 4000 nasty things that are found in cigarette smoke.

Chagpar So, when do you add in the counseling, is that something that should always be added in or only sometimes? Are there some people who benefit more from the counseling than from the nicotine? How do you sort that part out?

Bernstein It is a good question and there is no easy answer. Counseling is probably always offered. But counseling takes time so you have to work with the realities of people's lives, people have jobs, kids, commutes, etc., and in person counseling can be quite effective but most people cannot do that, they cannot go to a smoking cessation clinic a couple times a week. But what we do have available across the country, in all of North America really, is a toll free quitline 1-800-QUIT-NOW, which is the North American smoker's quitline. You can call that from any state including Canada for that matter and get a trained counselor on the phone, 7 days a week. They speak multiple languages. They are typically open 12 or more hours a day and that kind of counseling can be quite effective as well. So that is something that I tell my patients about and encourage them to make use of and that is private and confidential, and costs nothing and they can do it whenever it works for them.

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- Chagpar That seems to be something that is just an amazing service. Going back to the nicotine patches and lozenges, one thing that I think is amazing about the quitline is, it is free and there is absolutely no impediment to picking up the phone and calling somebody, especially if that is going to help you to quit. Are there programs that offer you the lozenges and the gum and the patches for free too? I mean is cost an issue for patients?
- Bernstein Cost can be an issue and there are ways to get these medicines for free sometimes or at reduced cost. Certainly here at Smilow Cancer Hospital we offer a smoking cessation treatment program with trained counselors and we provide counseling. We do not provide the medicines per se, but we make recommendations to the patient's doctors about what kinds of medicines they might prescribe depending where you live. Sometimes your local quitline will give away free nicotine patches or gum if you call them up. Sometimes if you have Medicaid or no insurance at all you can get more of those medicines. At this point, almost every insurance including Medicaid and Medicare covers smoking cessation medication, in fact, that is one of the wonderful parts of the Affordable Care Act, smoking cessation treatment must be covered under Medicaid, both medication and counseling. So this is really a terrific thing that we hope all smokers and their doctors take advantage of.
- Chagpar If you are a smoker, especially now with the expansion of the Affordable Care Act and ensuring that nicotine addiction and getting patches and counseling and so on is available, what is the success rate with those therapies? Do people actually quit or is it if you are lucky it works and if you are not so lucky it does not?
- Bernstein They do work and in fact they can work quite well. But we need to understand what that means, to work. Research shows us that after about a year of use, people who use these medicines about 20% to 30% of them will have quit. That may sound like a high number or that may sound like a low number depending on your point of view. But what we know about smoking is that it is a chronic disease. It is a chronic relapsing disease. In many ways it is similar to high blood pressure or diabetes in that sometimes people are in good control and sometimes not in good control. So if somebody can stay smoke free using the medicines that is great. If they have a relapse then they can make another quit attempt and try the medicines again or try the counseling again. It is not always the case. In fact, it is usually not the case that somebody can take these medicines for a month or two months or even three months and then quit forever, that would be uncommon but given what we know about addiction, it is probably not realistic either. We tend to think of smoking now more as a chronic relapsing disease. Sometimes people are abstinent and sometimes they are not and they need a little more help.
- Chagpar So, if 20% to 30% of people quit after a year and they stay quit, what happens to the other 70% to 80% of people. Is this a lost cause?

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Bernstein No, not at all, we know that the overwhelming majority of smokers want to quit. I mean the truth is very few smokers are happy with their addiction and almost all have insight into what is going on and the risks they are putting themselves at and their loved ones and most smokers do make a quit attempt at least once a year, well over half do. So, the ones who do not quit will try again at some point. We know that it takes about six to eight quit attempts for somebody to become a long term quitter. So really we need to encourage them and even if they stay smoke free for a month or two, that is a good job and when you are ready, you will try it again and at some point, you will be able to beat this addiction.

Chagpar I think it is really important for people not to lose hope that they can quit. We are going to talk more about smoking cessation, but for now we are going to take a break for a medical minute. Please stay tuned to learn more information about smoking cessation with my guest Dr. Steven Bernstein.

Medical

Minute Breast cancer is the most common cancer in women and in Connecticut alone approximately 3000 women will be diagnosed with breast cancer in 2014 and nearly 2000 nationwide. But there is new hope. With earlier detection, non-invasive treatments and novel therapies there are more options for patients to fight breast cancer than ever before. Women should schedule a baseline mammogram beginning at 40, or earlier if they have risk factors associated with the disease. With screening, early detection, and a healthy lifestyle breast cancer can be defeated. Clinical trials are currently underway at federally designated comprehensive cancer centers such as Yale Cancer Center and Smilow Cancer Hospital at Yale New Haven to make innovative new treatments available to patients. Digital breast tomosynthesis or 3D mammography is transforming breast screening by significantly reducing unnecessary procedures while picking up more cancer and eliminating some of fear and anxiety many women experience. This has been a medical minute brought you as a public service by Yale Cancer Center and Smilow Cancer Hospital at Yale-New Haven. More information is available at yalecancerCcenter.org.

Chagpar Welcome back to Yale Cancer Center Answers. This is Dr. Anees Chagpar and I am joined today by our guest Dr. Steven Bernstein. We are talking about smoking cessation, a huge problem in the US. Steve, give us an idea of the scope of how big a problem it is in the US. I mean how many millions of people smoke?

Bernstein In this country, 45 to 50 million people smoke, about 18% of the adult population smokes, it remains the #1 killer in the United States. It is completely preventable but over 4000 Americans die every year from tobacco products.

Chagpar Wow. That is just stunning. I want to get back to something you had mentioned in our earlier segment, which was about prevention, and you mentioned that again, this is a completely

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preventable disease. How exactly do we prevent people from smoking in the first place? How do we prevent them from getting the nicotine into their system to get hooked because it seems to me that is part of where the bleed is?

Bernstein It turns out in the United States most smokers take up the addiction, and we don't call it a habit, we call it an addiction, and they take it up when they are kid, when they are teens and adolescence. So in the US if you can get a kid to about age 18 and he or she is still a nonsmoker, they will probably stay a nonsmoker for the rest of their life. So, the key is really to target youth, adolescents, young folks and make sure that they do not become smokers and the tobacco control movement has had great success doing that over the last few decades and in a number of ways we have been able to a great extent de-normalize smoking, it is not cool anymore, it is not hip, it is not sexy, it is not fun, in fact it is yucky and expensive and I think more and more young people are getting that message, but aside from education in public service announcements, education regulation helps a lot too. It turns out young people are very price sensitive, they do not have jobs, they do not earn much money by and large so if you make cigarettes expensive it turns out young folks are less likely to buy them. So, the taxation policy at the state level, at the federal level, has been quite effective, the more expensive you make a pack of cigarettes the less likely young people are to take up the addiction.

Chagpar I grew up in Canada where I still remember on a pack of cigarettes, half the pack of cigarettes had to be a public service announcement about how this was going to rot your teeth or this was going to cause cancer. Really graphic images on half a pack of cigarettes, plus they taxed them until they were incredibly expensive, do those messages in the graphic art help as well?

Bernstein They do help as well and our friends in Canada have been really proactive about this and have done wonderful work. Other countries as well, like Australia have these very graphic even gruesome pictures on the packages of cigarettes and a good piece of that package is devoted to the health messages of what smoking can do to you and in this country it is a little more complicated, we have had these Surgeon General's warnings now for about 45 years on cigarettes but they are small, they take up just one side of the box, they are plain type. The FDA wanted to put more graphic images on cigarette packs, but as I recall the Supreme Court held that up and would not allow that because of first amendment considerations regarding the free speech rights of corporations so we have other considerations in this country that have unfortunately prevented us from being more aggressive with our public service messages.

Chagpar We talked a little bit about the youth and ensuring that our young people get the message loud and clear that smoking is not cool, is not sexy, it is really expensive, rots your teeth, it gives you bad breath and oh, yes, it causes cancer and a whole bunch of other terrible health problems. Are there other groups as well that we need to focus on in terms of making sure that they get the message about smoking and who might be particularly prone to smoke?

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- Bernstein It turns out that there are really important disparities at this point in terms of who smokes in this country. There are really two major groups. One is people from low income or low education backgrounds, so what we call low socio-economic status. In other words, smoking to some extent has become the disease of the poor and addiction of the poor and that is very important for us to understand and think about and try to do something about. It is also profoundly widespread in people with major mental illness likes schizophrenia and depression and other things like heroin addiction, smoking rates are high as 80%-90% even higher. So these two groups, poor folks and people with mental illness need very special care and attention in terms of helping them with their nicotine addiction.
- Chagpar In terms of the poor people one would think that very similar to the youth, they would be very price sensitive and so the idea of taxation might be an appropriate policy to help them to not get started smoking in the first place.
- Bernstein That is a great point and I think you are exactly right and in places like New York City which has been very aggressive with cigarette taxation, a pack of smokes in New York now I think is about \$11.
- Chagpar Wow.
- Bernstein They have really been able to cut the prevalence of smoking for everybody including poor folk. There has been this interesting argument over the years which I find kind of strange, if you make cigarettes more expensive, in effect that is what we call a regressive tax, it falls more heavily on poor people and we tend to think of regressive taxes as not that fair in this country, which is fine if you talking about income tax is about regressive tax on something that is going to kill you, to me that makes a whole lot of sense.
- Chagpar Especially when those are the people who are most prone. I now want to talk a little bit about the other two groups that you mentioned, the first one is heroin addicts, that 80% to 90% number just floored me. Is there data that cigarette smoking is kind of like a primer that in terms of drug utilization, you smoke first and then you gradually work your way up to more and more aggressive drugs or is it the reverse that if you shoot heroin that smoking kind of comes along for the ride.
- Bernstein It is unclear. There is this gateway hypothesis it is called where if you start with something like tobacco or marijuana, then you might graduate to what call harder drugs. There probably is something to that, but what we also know is that people addicted to one substance are more likely to be addicted to something else, probably because that is how their brains are wired and we do know that drugs like heroin or opioids, nicotine, cocaine, amphetamines all stimulate similar regions of the brain and release a chemical called dopamine, which feels good in the brain and occurs in the circuit that rewards pleasure and it becomes very reinforcing. So all of these drugs tend to do somewhat similar things in the brain and I am sure that plays a role in why these folks have multiple addictions.

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- Chagpar And I wonder whether that also ties into the whole theory of depression and the fact that people with mental illness, particularly depression, tend to smoke more. Whether it is that they kind of use smoking as a crutch and maybe we need to be focusing in this country a little bit more on how we can more proactively and constructively treat mental illness as opposed to having people self medicate.
- Bernstein The more I study addiction, including tobacco, the more I come to appreciate the power of depression as something that underlies a lot of addiction and I think it is widely under diagnosed and under treated in this country unfortunately and we need to be much more vigilant about understanding depression and how to treat it and maybe this recent tragic death of Robin Williams might help people to refocus or think about depression and the terrible toll it takes.
- Chagpar When we talk about depression, there are kind of underlying major depressive disorders and we think that has something to do with chemicals in the brain and then there is kind of the posttraumatic depression or psychosis that some people get after particular problems, and in the case of Robin Williams maybe that was exacerbated by his diagnosis of Parkinson's and I wonder about our cancer patients who frequently are given this diagnosis whether when they get that diagnosis are thrust more into depression and whether that could trigger smoking particularly in people who may have smoked in the past, gave it up and now are facing a new onset stress, what do you think about that?
- Bernstein We do know that any major life stressor might cause somebody to return to smoking even if they had been away from cigarettes for years. It might be the diagnosis of cancer. It could be something like getting a divorce or losing one's job. Those are unfortunately fairly common occurrences and so I think when somebody gets a piece of news like that, their family, their loved ones, and their physician need to be really vigilant, and among other things screened for tobacco use and offer some treatment in the moment should that happen.
- Chagpar Yeah and this might be another one of those places where counseling might be particularly helpful not only with regards to the nicotine addiction, but also the depression.
- Bernstein Yes, that is right and that needs to be treated simultaneously. We do know that there are some data to suggest that if you want to treat a smoker who is depressed, you probably should treat the depression first, get them on some medication for that, stabilize their mood and then you can do something about the smoking.
- Chagpar I want to pivot now into a little bit of your research, which has really been focusing on how we can treat people and use modern technology and health IT to help us in delivering this care. Can you tell us more about the work that you have been doing and how this could help smokers?
- Bernstein I work in the emergency department at Yale-New Hospital and the emergency department turns

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out to be a terrific place to identify smokers who are particularly from low-income groups. These folks tend to use emergency departments more than others and their access to primary care is not always as good as it might be. So for years, I have run clinical trials in the emergency department to identify smokers and begin treatment with medication and counseling. The most recent trial that we finished found that, in fact we could get smokers to quit who came into the emergency department. We got about 12% of them to quit at three months by giving them combinations of patches, gum, and referral to the Quitline and they did much better than the folks in the control. So that has been one focus of my work, another focus has been in the inpatient side of the hospital, folks who are admitted using the new electronic medical records that we have to help guide physicians as they treat smokers. So at Yale-New Haven, one of my studies results in a popup window when the doctor logs on to the patient's chart. If the patient is a smoker, this big window appears saying your patient smokes, would you like to offer him or her some treatment. If the doctors says, yes, then the record automatically kicks the doctor over to an order set, where he or she can order some treatment and refer to the Quitline and so forth. So I am very much interested in trying to use the power of computers and information technology to make it easier for doctors to do the right thing for smokers.

Chagpar That is fantastic. I know that I have certainly seen those big pop-ups and have always referred my patients over. It is interesting that you did some of your studies in the emergency room because we do not usually think of the emergency room as a place to do a clinical trial. We think of emergency rooms as places that you go when you are definitely ill for a one time deal. How did that work? Are these people really repeat frequent fliers to the emergency room or were you able to follow them up afterwards to make sure that they had stayed quit?

Bernstein We follow our patients afterwards, nobody comes to the emergency department to quit smoking, they come in because they have some acute illness or injury, but while they are there, we have a research assistant who can walk around and talk to the patients and screen them and if it turns out that they smoke, we ask them if they are interested in participating in our trial. It turns out most say, yes, because again they really want to do something about it. So we begin our treatment and we get their contact information and we follow them for up to one year after enrolment and we see how they are doing and like I said, so far they have been doing quite well.

Dr. Steven Bernstein is Professor of Emergency Medicine at Yale School of Medicine. We invite you to share your questions and comments. You can send them to canceranswers@yale.edu or you can leave a voicemail message at 888-234-4YCC and as an additional resource, archived programs are available in both audio and written form at yalecancercenter.org. I am Bruce Barber hoping you will join us again next Sunday evening at 6:00 for another edition of Yale Cancer Center Answers here at WNPR Connecticut's Public Media Source for news and ideas.