

Yale CANCER
CENTER
answers

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Hosts

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**Decreasing the Burden of
Cancer**

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Welcome to Yale Cancer Center Answers with doctors Francine Foss and Anees Chagpar. Dr. Foss is a Professor of Medical Oncology and Dermatology, specializing in the treatment of lymphomas. Dr. Chagpar is Associate Professor of Surgical Oncology and Director of the Breast Center at Smilow Cancer Hospital at Yale-New Haven. If you would like to join the conversation, you can contact the doctors directly. The address is canceranswers@yale.edu and the phone number is 1-888-234-4YCC. This week, Dr. Chagpar welcomes Dr. Cary Gross. Dr. Gross is Associate Professor of Medicine and Director of the COPPER Center at Yale Cancer Center. Here is Anees Chagpar.

Chagpar Why don't we start off by having you tell us a little bit about yourself and what you do and what COPPER is?

Gross I am a general internist, or a primary care provider, and I am a researcher here at Yale and my primary area of interest is cancer and understanding how we can help patients make more informed decisions about cancer screening, about cancer treatment options, and basically help generate new data that can inform decision making for both patients and for doctors.

Chagpar Terrific, and what is COPPER, aside from the metal of course?

Gross It is also an acronym for our center, and it stands for Cancer Outcomes, Policy and Effectiveness Research, but outcomes or cancer outcomes research, really means helping to understand how treatments, screening tests, or anything we do to patients affects them.

Chagpar Tell us a little bit more about the research that you are doing in COPPER? What are some of the interesting findings that are coming out, because it would seem to me that you have got a tremendous resource in terms of looking at outcomes, and a broad mandate as well?

Gross That is one of the challenges, there are many types of cancer and there are many new treatments that are being developed and being brought into clinical practice. So in our COPPER Center we have clinicians from a variety of specialties, we have surgeons, we have radiation oncologists, medical oncologists, other primary care docs. We also have health economists and a variety of other epidemiology and PhD specialists, but what we are trying to focus on is understanding when new treatments or new screening approaches are just starting to be used in practice, are they really helpful for patients? One of the challenges in our society is that I think we have a very strong belief in our culture that newer is better. We all want shiny new things and if you look at the way we frequently are advertising, even for laundry detergent, new and free are the words that are most commonly used in advertising because they are highly effective and my concern is that the same thing can hold true for cancer treatment. We are frequently advertising and we are frequently speaking to patients about the new treatment, but we are not 100% sure it is really better than the tried and true therapies. So in the COPPER Center what we are doing is we are working on evaluating some of these new treatments. Let me give you one example of one type of treatment that we are looking at. When women have early stage breast cancer, as you well know as a breast surgeon, after the surgical treatment one of the common approaches that clinicians use to help to

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prevent the cancer from returning is radiation therapy. So after a woman has breast conserving surgery and there is no visible cancer tumor remaining, the radiation can help to prevent the cancer from coming back again. And as you can imagine, over the course of the past 20 to 30 years as technology has progressed there have been new and exciting developments in terms of how to deliver, and how to treat with radiation. One of the new therapies is called breast brachytherapy where instead of using beams to shoot radiation from outside of the patient, for brachytherapy, a small balloon catheter is placed inside the breast and then the radiation is delivered internally, inside the breast tissue, around where the tumor was just removed from, and ideally this makes a lot of sense. The breast brachytherapy requires a shorter duration of treatment and these external beams can be delivered in about a week as opposed to coming back over 4 to 6 weeks of daily treatments like with external beam therapy, but it was not really clear whether patients were receiving the same outcomes because everybody would sign up for a shorter course of treatment, who would not want to have only one week's worth of treatment versus six weeks, but the tradeoff is you want to know if it is better or not. You do not want to take a one week treatment if it is going to have a worse outcome than the six week treatment. So what we did is we accessed Medicare claim's data, these are administrative claims, and all of the patient identifying information has been removed from these records so we are not actually looking at people's names or social security numbers or anything, but we do have the clinical information so we know the type of cancer and the type of surgery they received and who received this new brachytherapy and who received the tried and true external beam therapy. We found a couple of things. First, we were curious how often this new treatment was being used because there is not a lot of data out there comparing new versus old treatment so our first question was, how rapidly was this being adopted into clinical practice and what we found using data from 2008-2009 is that about 16% of women in the Medicare program who are receiving radiation therapy were getting this new brachytherapy. So about one out of six women now in the Medicare program were getting brachytherapy even though the benefits are unclear, and then we looked at how the use of brachytherapy varied across the country and what we found was that women living in some areas of the country were very unlikely to get brachytherapy. Basically it was not being used in some parts of the country, depending where you live. But for women living in other parts of the country, nearly 70% of them were getting brachytherapy, so to start, there is a huge variation depending on where you live and that impacts whether you are getting this new and largely unproven treatment. We then looked at outcomes of treatment and specifically we focused on the complication rate, we wanted to know, at least for the short term, did the likelihood of complications increase if you received brachytherapy and what we found was that women who received breast brachytherapy had a significantly higher chance of short-term complications, and these were not life threatening complications. I do not mean to scare our listeners who might have had brachytherapy. These were local complications of wound infection and need for additional procedures to remove fluid. So the take home point was that there were higher complication rates, not necessarily a higher risk of life threatening complications, but for us it has really raised the importance of doing more research to understand why these new treatments are being used and how can we generate more data to understand whether they are safe or effective?

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Chagpar When you talk about how things are marketed and new and free being the two key words, oftentimes new, at least when it comes to medical screening and treatments, is anything but free, and have you looked at cost associated with newer screenings and newer treatments, because particularly in this day and age when we turn on the news every night and you hear about the fiscal cliff and then we hear about sequestration and then we hear about the Affordable Care Act, it seems to me that kind of research is particularly important.

Gross That is a great point, even for people who have health insurance, often cancer can be financially challenging because of high co-pays, because of lifetime limits on how much your insurance will pay, and in fact, some studies have shown that health related costs are the number one cause of bankruptcy in our country. So when we are thinking about cancer cost, it is important to know that this is not only about the huge financial cost at the national level, I mean we are now in the trillions of dollars per year that we're spending on health care in our country with very little to show for it. In a recent publication by the Institute of Medicine they looked at the health care costs across 17 industrialized countries and found that we're spending about twice as much per capita in the US compared to other countries, and we finished dead last in many indicators of health. So at the population level were spending a lot on health and cancer, but also at the individual, at the patient level, it can be very expensive and sometimes can be debilitating to patients and to their families. So because of that the Yale COPPER Center had been focusing at looking at not only clinical outcomes, but also looking at costs, and in one study we looked at the use of new breast cancer screening modalities. I have a strong interest in women's health, hence this theme of breast cancer. Again, this is the same theme of the tried and true as analogous to the radiation, the external beam therapy that is tried and true that we compared to brachytherapy, here for breast cancer screening we look at traditional screening mammography and then we wanted to see how newer approaches to breast cancer screening are diffusing into clinical practice and how has that affected the cost of breast cancer care? So there are different types of mammography now. There is digital mammography. They have these computer aided detections, which can help the doctors to better see abnormal spots on a mammogram. We now have MRIs of the breast, which are sometimes being used for screening but there is not a lot of evidence that these are superior to the existing tried and true mammograms, particularly for older women. So we used Medicare data and we assessed the use of these new screening modalities and we also looked at the cost of care and what we found was that the Medicare programs were spending a total of over one billion dollars per year on breast cancer screening and this was remarkable not only because a billion is a big number, but also because there is very little evidence that is guiding our decision about who should be screened for breast cancer, particularly in women over the age of 65 or 70 years, so we are not really sure who should be screened and when we are screening these patients it is hard to know what the best approach is. We decided to breakdown the country into geographic regions, and as I mentioned we have over a billion dollars that we are spending from the Medicare program on breast cancer screening so we thought we'd look at which areas were spending more and which areas were spending less and compare the screening outcomes. Ideally, if you are getting your money's worth, if you are spending more on screening, women living in those geographic regions would perhaps having a lower likelihood of being diagnosed with metastatic cancer, because

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ideally the whole plan of screen is you want to catch the cancer early, treat it early before it can spread and become what we call metastatic disease. So when we compared different areas of the country, we looked at the high spending areas. These are places where they are spending twice as much on screening older patients for breast cancer and we found they are no less likely to be diagnosed with metastatic disease in those areas. So we are spending but we are not necessary getting better screening outcomes. For me this really underscored the importance of understanding how are we going to generate evidence that can help patients to make informed decision. Again, we do not want to say do not screen, what we want to be able to do is to tell patients, these are the risks and benefits for you and for someone like you, if you are a 75-year-old woman with a history of heart failure and your three sisters had breast cancer, for somebody like you these are the tests that we think are the most helpful and these are the risks and benefits. Right now we just do not have the evidence to do that yet.

Chagpar It sounds like you are moving towards more personalized approaches to assessing outcomes and cost in a meaningful way. We are going to talk more about that after we take a short break for a medical minute. Please stay tuned to learn more information about how we can decrease the burden of cancer with Dr. Cary Gross.

*Medical
Minute*

Breast cancer is the most common cancer in women. In Connecticut alone approximately 3000 women will be diagnosed with breast cancer this year, but there is new hope. Earlier detection, noninvasive treatments, and novel therapies provide more options for patients to fight breast cancer. Women should schedule a baseline mammogram beginning at age 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 to make innovative new treatments available to patients. A potential breakthrough and treating chemotherapy resistant breast cancer is now being studied at Yale combining BSI-101, a PARP inhibitor, with the chemotherapy drug irinotecan. This has been a medical minute brought to you as a public service by Yale Cancer Center. More information is available at yalecancercenter.org. You are listening to the WNPR Connecticut's public radio station.

Chagpar Welcome back to Yale Cancer Center Answers. This is Dr. Anees Chagpar and I am joined today by my guest Dr. Cary Gross. We are discussing decreasing the burden of cancer and right before the break Cary you were talking about the wonderful research that you are doing that is focused on improving outcomes, and reducing costs by taking a very critical look at how we screen and treat cancers. One of the things that struck me as we were talking and you were talking about breast cancer screening and whether in fact there is value in terms of using these newer modalities, particularly in older women, is the whole United States Preventive Services Task Force recommendations that came out that also tried to look at where the evidence was to get the maximum bang for your buck and how there was a lot of public outcry about reducing screening. How do you feel about that?

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- Gross That is a great question, because we certainly do not want to reduce access to tests that are effective. But what we do want to do is determine, using rigorous evidence, which tests or which treatments are definitely not effective and then tell people, you should be getting these tests. Nobody wants to ration care, but on the other hand no patient wants to get a treatment or test that is not helpful for them. So I think the US Preventive Services Task Force miss-stepped when they phrased their recommendations for women in their 40s when they said they should not be routinely getting screening mammography, and I think what they really meant was do not routinely, in the sense of do it all the time, without thinking about it, that type of routine like brushing your teeth, but the way it was interpreted was nobody should be getting mammograms in their 40s and I think what we should be telling our patients in their 40s is to really understand the benefits and risks of mammography and talk about them with your doctors.
- Chagpar I suppose the same thing applies to people in older age groups, like for somebody who is 90, who may be running five miles a day and playing tennis on the weekends and has an expected life of another 20 or 30 years, maybe, may actually want and benefit from tests more than say somebody who is 50, who is on dialysis and has coronary artery disease, end-stage liver failure.
- Gross Absolutely and it is a challenge because one of the important factors that influences whether a cancer screening will be helpful is your life expectancy, but then predicting life expectancy is not so easy. Two things makes this a challenge, one is, predicting is hard especially about the future, but the second aspect is that even if we did have really good instruments that can help us predict life expectancy, they are also tough conversations to have, a lot of doctors and patients do not feel comfortable talking about what may be a shorter life expectancy, and that is one aspect of our culture that I think we as a country need to get over, this hesitancy of talking about death, talking about end of life. Even if you are talking to someone and their life expectancy is less than 10 years, that is certainly not end of life, but it should affect the way you make decisions, maybe about undergoing a test that may not benefit you until 10 years from now, you should not do that test. So I think what we need as far as counseling older patients about screening are better tools to predict life expectancy, but also more training of providers, more training of physicians, or nurse practitioners, so that we feel comfortable speaking to patients about these tough issues so they can make informed choices.
- Chagpar The other tough topic to talk about is that all of those new technologies that you refer to, the MRIs and the latest, greatest, newest technology, many of them are embraced because they can find small cancers, they can find precancers, but some people I have talked to say this is leading to over diagnosis, so how do you know when a diagnosis is a diagnosis and when a diagnosis might be an over diagnosis and when tests are appropriate and when tests are just sensitive?
- Gross As our technology has progressed we can find smaller and smaller things inside the body, smaller tumors, many of which may not go on to cause any problem. We have known this about prostate cancer for a long time. There are many men who have early stage prostate cancer that have very

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favorable tumor characteristics and for many of these men they are not likely to see any health consequences of that tumor. What we say is that they are more likely to die with their cancer than from their cancer, but what we are recognizing more recently is the same phenomenon might be occurring for other cancer types. There is a recent study looking at breast cancer and they looked at 30 years' worth of mammography, or screening data, and they also looked at the trends in the diagnosis of cancers. And again, if you think about screening, if you screen more for a particular cancer type the idea is if screening truly is effective you would be catching more early stage cancers, but by catching it in an earlier stage, the whole point is preventing a late stage cancer. So if you are doing more screening, eventually, again this is at the population level, you should be finding higher numbers of early stage, and lower numbers of late stage. But what these investigators found is as mammography use grew, over a thirty year period, there was a tremendous increase in early stage cancers, but there was a very-very small decrease in late stage. Basically they added up all the early stage cancers they found and there are more than a million additional early stage cancers that were not accounted for by a decrease in late stage cancers. So that suggests that at the population level as you are doing more and more screening we are finding more than a million extra breast cancers, but we not necessarily decreasing the late stage. Now the real challenge is to take that information and use it to inform your decisions, so it does not mean mammography is not effective because many studies have shown it is effective, but on the other hand, these data show that some of the cancers that are being picked up may not go on to cause the patient any harm. Here is where the evidence comes to a grinding halt, we are not really sure how to tell which cancer is going to cause problems and which ones are not. What we really need to do is figure out how can we prognosticate for a women with a very small newly diagnosed cancer, particularly in women who might be older and have a lot of other health problems, whether she really needs to go on to receive chemotherapy or surgery, or if maybe that particular tumor is one of those very benign ones. One of those ones we call an over-diagnosed tumor.

Chagpar Because one would think that not only does that have cost implications for the entire system, treating people who probably would not need that treatment because the outcomes would be no different, and would have fundamental human costs as well in terms of giving people treatments with side effects that they did not necessarily need to have.

Gross Absolutely, in addition to the treatment related consequences, just the emotional toll of all of a sudden, boom you have cancer, you are a cancer survivor and if that information actually does not benefit somebody then it is hard to make an argument for digging to find it out in first place. We are at a fascinating time in our health care system because our technology is outpacing our ability to interpret the findings. One more interesting thing to note about some of these imaging tests like CAT scans is that they do involve radiation and by some counts the radiation that is being delivered to patients, not speaking about mammogram here, but in general the use of CAT scans in the medical field, we may be delivering so much radiation that were causing 20,000 or 30,000

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cancers per year just by exposing people to the CAT scan. So the irony is that as we are doing more looking for cancers, we may actually be causing more cancers. So, again this is just an argument for thinking about being careful about how we are using this new technology and understanding the risks as well as the benefits.

Chagpar It is indeed a very interesting time. Where do we take the research from here? How do we start answering some of those questions of who really needs to be screened and how? How do we personalize that treatment? We talk a lot on this show about personalized therapies and I think that plays in here as well in terms of personalized screening potential, figuring out who is going to get the most benefit and which cancers are over diagnosis and which are not. So where does the research go from here?

Gross So, we are at the cusp of a new generation of health-related research. As I mentioned earlier in our conversation, I have been using Medicare claims data, which is really useful, but that is nothing compared to actual patient reported outcome data. What we really need to do is link all these different sources of information together. We need to know for each patient, how they are being treated? What type of cancer they have? Are we are talking about screening or other health problems they have or cancer risk factors, and tie that into the patient reported outcomes. So ideally, when the patient presents to either the primary care doctor or to the breast surgeon, they should be completing these very brief focus questionnaires about their health status that should be intubated with their electronic medical record data and the health care system as we are seeing the patient. As the patients are progressing through the health care system, they are generating new data that can then be studied to help determine people's health choices and to determine which treatments are going to be most effective for them.

Chagpar Do you think there will come a day when, say Ms. Jones goes to the doctor and puts in all of her patient reported outcome information and there will be an algorithm in a computer somewhere that says, Ms. Jones you do not need a mammogram, but Ms. Smith over here, you do.

Gross Ideally, we want the patients to be in the driver's seat, so my vision would be to say, Ms. Jones for a woman like you, because you are say 90 years old and have severe health problems, there is probably a one in ten thousand chance of a mammogram helping you. However, there is a one in twenty chance you will end up needing a biopsy and it may end up being a one in fifty chance that you will have a cancer diagnosed that really would not cause you problems in the first place, I'm making all those numbers up obviously, but similarly for a different patient, you would give really tailored data so they can use that data to inform the decision making. My hope is that we are moving toward generating data that will inform their decisions, but not be too strict about how those data are being used.

Chagpar And you would wonder too as we think about over diagnosis particularly in fields like breast cancer, whether we will enter an era that will be more like what we have seen as the evolution in

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terms of prostate cancer, where some men with prostate cancer have this period of watchful surveillance, instead of having surgery or radiation, they are simply followed.

Gross Absolutely, and it is interesting to think about the fact that watchful waiting, or surveillance for prostate cancer, is an accepted treatment and for other types of cancer, people would cringe at that idea and probably because we do not have enough experience with those other cancer types to do that, but it is something to start exploring, which patients need treatment and which patient might benefit from other modalities or other approaches.

Dr. Cary Gross is Associate Professor of Medicine and Director of the COPPER Center at Yale Cancer Center. If you have questions or would like to add your comments, visit yalecancercenter.org where you can also get the podcast and find written transcripts of past programs. You are listening to the WNPR Health Forum on the Connecticut Public Broadcasting Network.