[MUSIC PLAYING]

IRIS WANG: I'm a physicist, but I'm going to touch something that is a little bit broader, because it's something that could be related to clinical management, because, as Lee mentioned, I am also a patient safety officer in our department. So the first time when we-- I just took over maybe three years ago-- and then the first time we have Roswell's system-- I think there's a talk later on, maybe tomorrow, talking about Roswell's, so you probably have heard of that.

So we use the Roswell's system, and the first batch of entries in there-- there were lots of pacemaker entries in there. So that's why I started to look into some literature, and tried to find out what we should do over here with regard to the pacemaker. I actually had a graduate student-- a master's student-- she was trying to do some Monte Carlo computation in terms of adults to pacemakers, so that's why I'm here to try to talk about pacemakers.

But in any case, I'm not an expert about pacemakers, but I tried to look at literature and give you some overview of what we should manage in terms of electronic devices-- actually, cardiac, not only pacemaker-- nowadays, we have defibrillators, also.

So Dr. Mohota-- if you were here with Dr. Mohota, he mentioned about life expectancy in his talk I thought it's interesting because many other countries live longer than us in the US, right? So our life expectancy is about 78, or a little bit more than that. So my first question to you-- do think that we live longer than, say, 20 years ago? Yes, right?

So the answer is yes, because-- I just took some numbers from the website and plotted in Excel to give you some-- so that's the trend. If you look at from the 50s to nowadays, it keeps increasing from even 60-- below 70-- now we're at 78.

So because people are living longer now-- and if you look at the graph on the right-- look at the bottom curve, that's the cyan curve, 65 years or over-- it's increased, because we live longer, and we have lots of aging population now-- baby boomers, or whatever they're called in the US-- so now we have lots of aging population. They

live longer.

So that's why when we look at-- we got lots of entries in our Roswell's system-- why? Because we have pacemaker patients. So if you're thinking, oh, it seems like we have lots more pacemaker patients nowadays, that's probably true, because we do have patients live longer and have cardiac devices implanted.

So the next slide-- before I show you the slide here, I want just a show of hands-- how many of you are dosimetrists? I see a majority of you. So some of you are therapists, right? So how many of you are therapists? The rest of them are therapists.

So what I'm talking about dosimetrists and therapists-- you're part of this management of a pacemaker, right? So if you're a therapist, you're not at treatment, but at CT simulation. So first thing, you see an image-- you do a scout image. This is not really a scout-- I used a DRR-- it's a fake scout image, because it's hard to get to this GE to get a scout image, so I used DRR-- but you see a scout image.

Before that, you didn't know anything about this patient-- has anything in their body-- and you saw this. So as a therapist, you see this, and the first question-- oh, is that a pacemaker, or whatever the device is? Yeah, you know that it's true. There is some sort of device. And your reaction would be like, oh, why did nobody tell us ahead of time? Because before that, the nurse, the physician-- they probably see the consult and everything was read ahead of you, but nobody told you about that. But then you have to talk to the physician, and you decide to proceed with the CT scan, so you finished the CT scan.

The next step will go to the dosimetrist, after the planning, and then another surprise to the dosimetrist, right? Because nobody told you there is a pacemaker in this patient. And so your reaction would be, oh, you see this, do I have to contour this? Yes, you do have to contour it. So that's extra work for you, but unfortunately, you have to contour it.

So then you need to think about-- what is the dose limit to this pacemaker that I need to plan to, and what's the planning technique you need to use, especially when

it's very close to the target. So there are lots of things you have to do.

So what I'm going to talk about today-- this is the outline of my talk. So I'll give you some background about what the pacemaker is for, and a little bit structured. I'm not an expert of pacemakers, but I'll give you some images, just to explain a little bit. And in terms of physics-- I'm a physicist, so I have to talk a little bit about physics-- so I'm going to focus on the megavoltage X-ray today, not touching other areas like protons and other things.

So I'm going to talk about the photon interaction. You have all learned in your courses, so you should have remembered that. And some list of errors that could occur if something accidentally caused damage to a pacemaker. Out-of-field dose-- that's important-- especially for dosimetry, you need to understand that-- because we don't want any direct beam to the pacemaker, so we need to understand what is an out-of-field dose, and so on.

And some guidelines, and policy and procedure. So that's actually very important, because the pacemaker-- I talked to one dosimetrist just now-- it didn't change much from 20 years ago up to now. The technology changed, the pacemaker components changed, but in terms of the study, the data-- there are some reports that say, oh, there's an error because of this, there's an error because of that-- but still scattered data.

So we need to follow a standard procedure so that we can make sure we safely deliver the dose to the patient with a pacemaker. I keep saying pacemaker, but it's a device-- electronic cardiac device-- but we just use the pacemaker term.

So the background knowledge we need to know is, what is the pacemaker for? For a patient who has arrhythmia. Arrhythmia is basically just abnormal heart rhythms, so it could be bradycardia, which is slow, or tachycardia-- fast-- or some irregularity of the heart. And we have a natural pacemaker in our heart-- that's why our heartbeat-- rhythmatically, because we have a natural pacemaker.

This is the natural pacemaker in our heart. It's called an SA node-- sinoatrial node-- and it periodically generates impulses-- we call that a depolarization pulse-- so that all the chambers will beat in unison. So the two atria beat first, and then the two ventricles beat second.

But some of the patients-- they have problems, because of heart conditions. It could be abnormal rhythm from the SA node-- that's our natural pacemaker-- it does not work. Or some interruption-- you see those yellow lines in the graph in the picture over here-- those are the conduction paths. So if that gets interrupted, that could pose a problem, so that's another condition that could cause the arrhythmia.

Thirdly-- I mean maybe there are more. Again, I'm not a cardiologist, so this is just based on my knowledge here. There could be impulses from other heart tissue. So the SA node itself actually is just a specialized myocardial cell-- it's specialized-- still a part of the heart muscle. The muscles-- they have they can generate electric pulse, so it could be some other part of the heart that could generate the pulse that's causing the problem.

So those are the potential causes, and nowadays, because of the technology development, there are more advanced cardiac devices that could help those patients, so cardiologists just implant the artificial electronic device into the patient, and patients carry that, and that actually prolongs the patient's life expectancy. That's because, again, heart condition is the major cause of death.

So that's the physiological background-- that's the best I can do, because I don't know more than that. Let's look at the pacemakers themselves. We use cardiac implantable electronic devices, and the list on the bottom there-- the four pictures on each site-- there are four different major vendors. In the US, I don't think we have lots of electronics, but a majority of the pacemakers we saw in our clinic are from the other three-- St. Jude, Medtronic, and Boston Scientific.

The middle picture over there-- that's the lead of the pacemaker. So the lead is from the pacemaker-- goes all the way into the chamber of the heart. And the tip of that lead is an electrode, so that's touching the inner chamber heart wall, so that gives the electric impulse into the heart muscle.

There are lots of different categories of pacemakers, and nowadays-- why did I say pacemaker-- CIED-- I will use CIED for now-- because pacemakers-- one of the categories-- is Implantable Cardiac Pacemakers-- ICP. And in newer models, we also have Implantable Cardioverter Defibrillators-- ICD. So the defibrillator is because some patients-- because of the heart irregularity, they need a big shock for a

moment to get their heart beating, so that's the purpose of the defibrillator.

So ICP and ICD-- there could be other categories-- more details-- but those are the things-- we will just separate them-- ICP and ICD. So I have a question for you. Which one do you think is more radiation-sensitive-- ICP or ICD? So who thinks it's ICP? OK, so I assume all the remaining votes think that it's ICD-- D is defibrillator.

Now I have an answer later on, so I'm not giving you the answer now. These newer ICDs are dual-function-- most of them are dual-function-- it's both a pacemaker and defibrillator. So when we say ICD, very likely it's also a pacemaker, but in addition, there is a functional defibrillator, too. So the answer to that-- and I think you want to know the answer. I wanted to leave it until the end, but I think from what I have read, the defibrillators could be more sensitive than pacemakers, but depending on the vendor, manufacturer, and the components.

All right, so we have an X-ray-- we know the case-- we see those pacemakers. But what's inside the pacemaker? So on the right side, this is an X-ray of a patient with a pacemaker, and you see this is the major part-- we call that a pulse generator part-- and then there is a lead, and the lead goes all the way into the chamber.

Some of the pacemakers could be-- maybe I should go back. So if you can see this picture over here, there seems like only one channel over here, and some of them-- they have two channels. So there is a dual-chamber or single-chamber pacemaker. This one is a CIED. The reason I'm saying CIED is it's not only a pacemaker-- it's also a defibrillator. But how do you tell that it's a defibrillator?

Because you see this and that-- it's called shock coils. So when the patient has the lead with shock coils, those are defibrillators. Sorry. There. It's not very clear-- it's clear on mine, but it's more attenuation, and so it's a little bit thicker than the lead-- if you see the lead over here, it's like thinner [INAUDIBLE], but there is a thicker part here. So that's the shock coils. So when you see that, that means that's a defibrillator. Remember that it could be more sensitive for defibrillators-- then you need to be paying attention to that, also.

All right, so let's take a look at the right side. That's the pulse generator part. So basically, the lead is just a wire and some electrodes. And this part is the pulse

generator, and the top part of the pulse generator-- the yellow part-- we call the header. The header is basically a connector between the pulse generator and the lead.

And also, there is a small part over there, with the little oval circle over here-- that's the company information, and even the pacemaker serial number with the patient identifier-- that's over there. The red box I have over there-- that's the major circuitry over there. That's like a little computer. It stores information, sends information to the-- it's like a computer-- and generates the pulse, and gives off the electric charge, and also stores the information.

There's a timer inside there. The capacitors are for the charges. So lots of things there-- there could be lots of like tiny, tiny semiconductor chips. The newer models of ICP or ICD use a technology called CMOS, and there are some publications saying that CMOS could be more radiation-sensitive than the older model.

But now another thing is that they use that, and then we have a smaller pacemaker. So my student actually got-- I didn't get a picture because I couldn't find her-- so she got two different pacemakers. One is from 20 years ago-- it's really, really big-- and the current one is like this. So it's smaller-- that's beneficial to the patient. However, because it's smaller, maybe not enough shielding, or not metal covering-- could be more radiation-sensitive.

But we don't know, because basically had lots of data reported saying, oh, this dose gives us this trouble, and this dose gives us this trouble. But some of them, they say oh, 0.2 gram gives them trouble, and some of them say, oh, I give the radiation in vitro 30 grams-- no change for the pacemaker. So it's kind of very sporadic and unpredictable, I'll say.

But anyway, so we need to understand what's inside there. But that's the important part, because if there's damage over there, that's changing the program of the pacemaker. And there is a battery over there. So radiation could damage the battery, also. So let's go to the next slide.

As a physicist, I need to talk a little bit about physics. So the reason for this is, I want to go to the last step of this slide to show you something. So the first one is very easy to understand. No energy deposit-- absorbed, or whatever-- in that process.

Basically, the photons just scattered. That's called coherent scattering. We usually ignore that part, because it's just scattering-- no dose to the patient or pacemaker.

Compton scattering. So we see that photon coming in, electron ejected, and there is a lower-energy photon that comes out. But if we look here, it's more towards the outer shell of the electron. When you have some process when the photon is coming in close to the nucleus-- inner shell electrons-- you get photoelectric. That's complete deposit of the dose, and you get electrons.

So what we are doing in radiation therapy-- we use megavoltage. So megavoltage-- we use 6 MV, 15, 10, 23. So lots of them-- in the radiology department, they use kV-- so we regarded only these three. So in our department, another process we are looking at is pair production, because when the photon energy is above 1.02 MeV, you get pair production. But that's another thing to deposit dose to the patient or to the electronic device.

So all these four we know pretty well, actually. But if you look at this, the photon is close to the nucleus, but there is no one nuclear reaction in there-- it's only changing the photon into two electrons, positron and electron.

So last one-- that's the most important part when we talk about pacemakers. It's called photon disintegration. I couldn't find a graph for that, even from [INAUDIBLE], so I just gave you a formula over here. So here, gamma is the photon-- X-ray-- even though it says gamma, it's X-ray in our department. Or it could be gamma ray. Maybe it's cobalt.

And this is just an element where the A number is the mass number, and the Z number is the atomic number. So this-- there is a nuclear reaction in there, because when the photon hits the nucleus, the nucleus got changed. It made a neutron, and then the element itself changed-- it didn't change the chemical property, it still has the same Z number. however, the mass number subtracts 1, because you generate a neutron, so the total, adding together, is the same.

So that's the one giving us trouble when we're talking about CIED. So you probably have heard that neutrons could damage the pacemaker. It's very sporadic, it's scattered everywhere, so you're not sure when it's going to happen-- but because it's a high-LET particle, the damage is more severe. So that's why we need to pay

attention to this process-- it's called photon disintegration.

But this one-- it's not like at 6 MV it's going to happen, because lots of the material-- we call that cross-section of this-- requires higher energy of photons, like 6 MeV, or 8 MeV, or even above that. So because we have a spectrum, anything we plug in-- so you know the difference between MeV and MV, right? So if it's 8 MeV, it doesn't mean-- say, 10 MV will get lots of 8 MeV photons, because it's the spectrum-- it's in the tail part of it.

So photons, neutrons-- you have to pay attention to any energy that's above 10 MV-- there's photoneutron contamination. So that's actually the major message when I look at the literature. They have reported lots of incidents about pacemakers. There's something-- 6 MV-- there's some cases reported, but if you look at the ratio between the higher energy and lower energy, lots of reports are higher energy-- above 10 MV.

So that's basically why we talk about physics here, because we want to know that there's neutron production when the energy is above 10 MV. So let's look at what kind of errors we could get. There are a lot of different definitions-- how that's resetting, reprogramming-- those things. So I'll stick to one literature and how they describe that.

So they describe-- it could be altered stimulation, in terms of amplitude or frequency, and altered sensing, because those leads sense the charges, and then they deliver that-- so altering the sensing, and inhibited stimulation, and change in operation mode. So there are different-- it could be not detecting the heart, but just [INAUDIBLE] that's called asynchronized mode stimulation.

Battery depletion-- that says, there's a battery over there-- that could cause a problem. And altered electrode sensing, and loss of telemetry-- cardiologists just keep collecting the data and sending out-- there could be a loss of that-- the tiny, tiny computer there got damaged-- and reset to the default setting, and loss of function.

So that's the first errors I mentioned there-- they are not only for ICP, they're also for ICD. But in addition to that, ICD has additional problems, because there's additional

function for the ICD-- it's to treat the tachycardia, so it's basically the antitachyarrhythmia therapy-- that's a function of the defibrillator. And then that could be inhibited, because of radiation, if it's damaged. And basically, the ICD has a very high-energy electric charge, or the shock, but that shock can be changed because of the damage of that.

This is additional things, because we are dealing with ionizing radiation, but there could be-- we have new technology talking about MRI-guided radiation therapy, so you know that pacemaker patients have to be really careful in the MRI systems. And even for LINACs, we have radio frequency energy in there, but the [INAUDIBLE] LINAC, usually, is not a big concern-- we use [INAUDIBLE] or magnetrons.

But that's something-- because if the patient, for lower energy, experienced some transient effect that's not very severe, it could be because of this-- some of the EMI in there. So now we know that there could be potential errors that damage the pacemaker, and we need to know how do we protect the patient with this CIED.

There are two documentations that I'm going to talk about in terms of the out-of-field. Basically, we don't want to treat the patient with direct radiation. That's one way-- a very simple way-- we should do to make sure that there is no direct radiation. That's the recommendation from AAPM TG34, which was published in 1994-- I don't know the year-- 25 years ago.

So that could be outdated, however this statement is true all the time. You want to make sure the pacemaker is not in the direct radiation. So there's a recent publication from AAPM, the TG158, talking about out-of-field radiation doses. How do you evaluate the out-of-field radiation dose? That is not limited to only to the CIED, but say if you have a pregnancy patient-- how far you want to keep that, how do you do the shield-- you need to estimate the out-of-field dose.

So this is important, because now we are dealing with the out-of-field radiation, instead of directly. Directly, the treatment plan-- we simply calculate perfect amounts perfectly-- it should be perfect, within a certain tolerance. But when you're talking about out-of-field, there's lots of different things going on, so you have to make sure you estimate the dose correctly.

So let's go back a little bit to 25 years ago-- should not be treated with betatron. I

don't know if anybody knows about-- who knows about what is a betatron? There's some people there. Look at hair, right? I've never seen a betatron, but I just looked at it when I studied my physics course, and looked at that, and what is a betatron. So there's a magnet in there-- basically, the acceleration part is a magnet-- so definitely you don't want to use it.

But it's outdated. We don't have betatrons anymore. Most are [INAUDIBLE] magnetrons-- we don't see many. But anyway, so that's part of the TG34. And should not be in the direct beam-- it's common sense nowadays. And the dose should be estimated before radiation. Even though it's out-of-field, it doesn't mean that the dose is safe, so we need to estimate the dose. That's still true.

And if greater than 2 gray, it should be checked before the treatment, and also possibly-- they say possibly, but I'll say that's the recommendation-- you do a weekly check if it's above 2 gray. That's the TG34 recommendation. The reason for that is even in the old days, a functional change in the pacemaker had been observed between the 2 and 10 grey range.

So this is common sense nowadays, becomes that, but we need to deal with the out-of-field radiation. So out-of-field-- you have a LINAC here, a patient here, and then-- here it's probably just a pregnancy patient. But anyway, the treatment field-- the primary field-- is over here, so what kind of sources? There are three sources of the out-of-field radiation.

Part of it is the leakage from the treatment head, and the scatter from-- we call that collimator scatter. And then the third source is the scatter from the patient. So that's the three sources of the out-of-field radiation. Internal scatter-- we call that patient scatter. Usually it's dominant when the area that you have concern with is very close to the field, because the scatter of the patient-- so that's usually dominant among of the three of them.

Collimator scatter is never dominant, but it's always there. From even here-- there-- it's still there, because it's scattered. And the last one is the head leakage. We have a shielding of the LINAC head. However, it's not 100%. So there's still some number of leakage from that. So that's the leakage.

Usually for this case, it's dominant at distance. So say, if you're treating a head and

neck-- and so this is a fetus example, so the is right here-- but there is still a good amount of leakage through the human head, so you may have to for this case. So those are the three sources of out-of-field radiation.

Let's look at some properties or characteristics of those out-of-fields. So they're softer. Not the leakage-- the leakage part could be a similar energy, but then the scatter is usually lower energy. And decrease with distance, especially for patient scatter. And increase with field size, especially for patient scatter. So you know that a large field size gets more scatter when you're close to the field edge.

So this is the newer [INAUDIBLE], so think about TG34-- open field. Now we are doing [INAUDIBLE] MRT, all different conformal-- and lots of modulation we give to the patient, in order to conform to the target, and not damage-- in order to spare the normal tissues. But with the increase of the modulation, you have to deliver more MUs. Basically, the head leakage is proportional to the number of MUs, so the more MUs you deliver, the more head leakage. So that's something you have to think about, but that's only because the head leakage is usually dominant when it's far away from the field.

So again-- I'll go through really quick, because we didn't have the understanding of the neutrons. So the neutrons are coming from the scatter from the treatment head, and usually the neutrons from the treatment head are relatively isotopic, so it's everywhere. And the fullness of the neutrons also increases linearly with the MU.

So if you have to use a higher energy, remember that if you deliver more MUs-- more neutrons are there. So this is an example from Varian accelerator from 10 MV to 15 MV-- the neutron numbers influence is 10 times. So if you think, oh, I need to reduce the number-- if you cannot go to 6 MV, maybe I should just use 10 instead of 15, or 23, or 18.

And we have flattening filter-free LINACs-- what about those? They are a softer beam, and the out-of-field radiation dose actually decreased a little bit if you're the same energy-- 6 MV or 10 MV versus 10 MV [INAUDIBLE].

Physical wedges-- so think about this. When you have physical wedge, there could be neutrons, there could be more scatter. So one way to reduce the dose to the

pacemaker-- maybe you don't use a physical wedge-- you have other ways-- other modulation, or other things-- EDW, or whatever-- so you don't have to use it. So there is a mention about physical wedges.

So the last two points I'm going to point out here, especially for the dosimetrists-- you do that computation, you contour the CIED, and then you calculate, and say, oh, you tell the physician-- we're below 2 grey. How confident are you about that-- below 2 grey? It may not be right, because our TPS is not accurate when it's far away from the field edge, especially when it's greater than 3 cm from the field edge, or it's below the 5% isodose.

Lots of TPS-- they study differently-- so a majority of the TPS would underestimate the dose by maybe 30% or 40%-- that's the published values. But some publications say it could be an overestimate. Overestimate is a little bit better, because it's overestimate, and you say it's below 2 grey-- it's still below 2 grey. However, you probably will have to compromise your plan a little bit, because of that-- it tells you it's already reached 2 grey, and I have to compromise my target coverage. So that's not also not very good. But just keep that in mind-- the treatment planning system does not give you an accurate number when it's more than 3 centimeters from field edge.

So that's why physicists-- we do all the other things-- that's why. My student did Monte Carlo to try to work on that, and I'm going to skip this part, because I don't think the audience will be interested in that. But measurement-- that's more work for us. So now, we know that there is a number-- either your generate from the TPS, or if you have a physicist measure it-- you know what dose you are going to deliver through the device, and then what is our limit.

Again, there are different guidelines, and the guidelines-- majorly, they are focused on cumulative dose-- that's why I'm talking about cumulative dose here-- but there are some other factors could be involved. For example, the dose rate-- what about dose rate? Lots of questions marks. But because of the guidelines, they stick to one factor over here, so we're going to focus on the cumulative dose.

Risk categories, and how do we manage patients? So I'm just going to go over this. So in terms of cumulative dose, we know that TG34 is 2 grey, but it doesn't include

the modern technologies, and even the ICDs. And there's manufacturers-- they give us different numbers. Some of them are reluctant to give any number, because they say below 1 grey is safe, and then you get an incident or damage-- that's not good, right? So some of them don't even have any safe dose limit.

There's one organization called Heart Rhythm Society. They are a bunch of, I think, cardiology-- whatever physicians there-- none of them are radiation oncologists, or in that group, but they give a recommendation of five grey. Maybe they look at some of the research, and say, oh, 5-- at least you should keep the pacemaker dose below 5 grey. So now I have 2 gray and 5 grey.

And the Dutch-- DSRO I put here, because I want to-- this is the Dutch Society of Radiation Oncology. That's very popular these days. Lots of people refer to that, because they give a very detailed guideline of how to manage patients. They gave risk categories, so that's what I'm going to talk about-- what are the risk categories of the pacemaker patients.

And there's the AAPM task group-- it should try to update the TG34-- it's called TG203. But their publication is not published yet, so I cannot report anything. But I did look at some of the slides they provided, so that gives you some information from them. But they used a similar approach as the Dutch group-- used risk categories. That's what I'm going to talk about next.

Before I go into the risk categories, let's look at the manufacturers' recommendations. So those are the four major manufacturers of CIEDs-- Biotronic, Boston Scientific, Medtronic, and St. Jude. So there are device checks-- all of them recommend at least you should do that after the radiation therapy-- check it-- and some recommend you should do that before and after, and then during or after, or specific to patient-- you should monitor things like that. So different recommendations from different manufacturers.

In terms of dose-- this is Biotronic-- this is old, because the publication here is referred to as, already, old documentation from there. So maybe their newer documentation is different-- so this is what I'm referring from this reference over here. ICP and ICD-- both are at 2 grey. But for the Medtronic, it gives 5 gray is safe for ICP, but then for the defibrillator, they have different models of ICDS, so some

are 1 grey, some are 2 grey, some are 5 grey-- so depending on how they structure components inside that device.

So keep in mind here, there's 1 grey here. So 1 grey doesn't mean-- so if you follow the TG34 2 grey, those ICDS could be damaged, because there's more than 1 grey. And also, again, the 10 MV limit-- there are some manufacturers suggesting that.

So let's look at the Dutch group. They have these very nice risk categories. So 2 grey, 2 to 10, and 10 gray-- that's in terms of cumulative dose. And then they have a separate-- in terms of patient. Some of the patients-- they're fully dependent on the pacemaker. If there's any damage, that could be totally wrong.

But some of the patients-- they're sort of independent. It's only when it's needed, or occasionally there's an irregularity, and then the pacemaker will sense that. So it could be dependent or non-dependent, so that's the two different areas. Anything below 2 grey and patient independent-- that's the low-risk group. So that's actually-- we want to see. We want to keep that below 2 grey, but then the patient is also not fully dependent on the pacemaker.

In the medium-risk group are patients dependent on the pacemaker, or either it's below the 2 grey or below the 10 grey, so that's the yellow area. High-risk area-- anything above the 10 grey-- that's high risk. So the TG203-- from their slides they presented in the AAPM meeting-- they mentioned that they are going to use the same approach-- with the risk categories-- and very likely, instead of 10 grey, they will use a 2 to 5 grey as medium-risk, and above 5 grey as high-risk. But we'll see when they finalize their publication. One of the authors in the Dutch group-- he is also on this TG203.

In terms of pacemaker dependency-- again, I'm not an expert in the pacemakers, so I had to look at the literature. And I heard from some physicians-- some patients may be fully 100%, but when you see 100% of patients depend on the pacemaker-- maybe not many of them. And then again, not many may be fully non-dependent on the pacemaker, because why did they have the pacemaker implanted in the first place-- because they need some help. And there's intermediate area.

So in this previous group-- either you're dependent or not. So that's something that we have to be aware of-- how do we find out from the cardiologist whether the

patient is dependent or non-dependent-- meaning that if the pacemaker has malfunctioned, is there going to be a big danger to the patient health, or life, or that.

So the Dutch group have a very nice workflow and [INAUDIBLE]. You can use that as a baseline-- the guideline for your policy and procedure. So here is what they do. When they manage the patient with CIED, first you need to communicate with the cardiologist, and also the patient, about potential risk of the radiation damage.

And again, you need to determine whether the patient is pacing-dependent or not dependent. So there are guidelines of how you do the check-- those kinds of things. And again-- I don't know how many times I've mentioned this-- the 10 MV limit. And we need to estimate the dose to the CIED. We need to think about the out-of-field dose part.

And as dosimetrists, you do your optimization, you do your planning-- you want to make sure the dose to the CIED is as low as achievable. So you want to make sure it's as low as achievable. You try to meet that 2 grey or below, but then if sometimes you have to have a higher dose, then you try to make it possible to be as low as possible.

So this picture over here-- that's part of the-- it's very famous now, so everybody refers to this picture, because if we are treating a head and neck-- a pacemaker usually is in the upper chest area-- it's very likely you will give a high dose to the pacemaker. But there's good news, because your TPS actually could calculate pretty accurately. But that's not good for the patient, because it's potentially higher dose.

So then, that requires your treatment planning technique-- try to reduce that. And the yellow area over here-- that's very likely that you can still be above the 2 grey-- still potentially [INAUDIBLE]. So then you need to do a little bit more effort to reduce that dose.

But look at the green area. And don't say, oh, the pacemaker is far away-- we're treating prostate. Don't worry about the pacemaker, it doesn't matter. And we are treating the GYN, the pelvis-- it doesn't matter. But it still matters, right? Especially when you do the 3D conformal, you use high energy, so you still need to make sure you use the correct energy. Don't ever use a high energy because there's neutrons

there that could potentially damage the pacemaker, even though it's far away. The dose limit you can achieve-- you don't even have to calculate it. It's definitely below 2 grey.

So they have some recommendations-- how do you manage those patients? Remember, they have three categories-- low, medium, and high. So low risk-- we need to monitor the patient. We do that for all the patients-- audio and video monitoring of the patient. And in case of ICD, they recommend to turn off the tachycardia therapy, but that's up to our physician to decide. And you need to communicate with the cardiologist and do some checkups.

The intermediate risk-- you need to get a closer look during the treatment. So there's [INAUDIBLE] and possibly, if you have that available-- you have some external pacing available, in case the patient has some issues. And there should be a trained cardiologist in 10 minutes distance available, in case there's something. So that's for the medium risk.

High risk-- hopefully we'll never have a high-risk patient, but if that's the case-- they have their recommendations. It's literally continue the ECG monitoring, and all the things available, and check the pacemaker within 24 hours. So that's the Dutch recommendations.

So now, let's come to our individual department-- what you will do with all this-- even though it's more than 25 years, and there is a change of technology, but the data could be-- 0.2 grey could cause problems, 20 grey could not cause problems-- there could be neutrons everywhere if you use high energy. So what should we do?

We should have policy and procedure. Because we have a multiple-disciplinary team-- it involves the nurse, the physician, the dosimetrist, therapist, physicist-- so everybody's there. So in terms of the workflow, you need to follow each step so that we make sure we safely treat this patient with a CIED.

In our department-- so I just give an example. This is our department. We have some points that we think are important in the whole process. First of all is to identify those patients who have these CIEDs, because if you don't identify those patients, you can put the patient on the treatment table-- you don't know that. I'll

deliver 23 MV. The same therapist may not see that, because we didn't even scan the part in the chest, and we don't know anything about it. That's dangerous.

So identify patients with a CIED-- it's the first step. And you can identify that when you see the patient-- you give the questionnaire to the patient. But if you don't put that information in the EHR, or whatever patient chart-- the downstream-- the therapist, the dosimetrist, the physicist-- we don't know about it. So we need to have some alert system in the patient chart so everybody can see that downstream.

Because we have all different areas-- especially, you probably have to involve the manufacturer technician or a cardiologist-- so then how do you manage that? You should follow some guidelines, or you have your own department, depending on the availability, or whatever you need to ensure the patient's being-- in case there's an incident or event happening.

And we should follow the published guidelines-- more conservatively-- because even though the data is-- could be a range everywhere, but the lower the dose, the better, so we need to follow those guidelines. And if it's available from the manufacturer, you need to follow that. If it's below the 2 grey, for example-- the ICD could be 1 grey, then you need to follow that 1 grey instead of 2 grey.

So here's our-- how do we detect the patients with the CIED? So we have three steps before the CT simulation. Our CCAs-- they hand out a review form, or questionnaire, to the patient. In that questionnaire, there is one question about-- do you have an implanted electronic device. A patient could answer that-- maybe the patient-- they have that, they just don't check it. That's possible too, but that's the first step. You want to let the patient tell you whether there is one or not.

The next one will go to the nurse. The nurse will verify the form, but then at that time, the nurse will ask the same question again to the patient, because when that nurse reviews each item, the nurse will ask the patient-- do you have a pacemaker or an electronic device?

And then the physician and his team-- like a PA-- they will do the consult with the patient. And then that's the next step-- you want to see whether the patient has an electronic device or not. If there is one, the nursing staff or the physician-- they will put that alert into the patient chart, and they will scan a patient-- if the patient has

that available-- will scan the patient's device card into the EMR.

Next step is going to the CT simulation. Assuming the first three will detect, but it may not be 100%, because a patient may not tell anything. Then CT therapists-- they will do another time out when they do their CT set time out. They will verify if there is a presence or absence of the CIED. If there is a CIED but there is no alert or information, they are going to put that information, so then downstream, in that dosimetry and physics, when we plan and review that-- because sometimes, yeah, if you're treating breasts, or you're treating lungs, you probably see that in the image-- but sometimes you don't see it, and then that's an important step.

So this is just a device card, and this is the notification-- we use Mosaic. You can use other systems, as long as you have something. So whenever we open that patient, this message will say, oh, there's a pacemaker, and dosimetry will know-- oh, I should contour that, or if it's not in the image, we should use lower energy, at least.

Dosimetrists-- we already touched everything over here. Yes, you do have to contour it and give a dose, but in our department, we have the policy if it's below 2 grey, or below the manufacturer's recommended dose level, it's OK. So then the next step-- physics will review that-- that probably will go through. But if it's above 2 grey, they need to notify the physicist or the physician.

And basically, there is going to be a discussion happening, and maybe a special meeting among them-- how do we manage that? Is that OK or not OK? What other options should we have, or what next step-- how do we monitor the patient? That's the next step. Physics procedure-- review it, make sure there's alerts, and verify the plan. But if there's a problem, we will initiate the discussion with the physician, or whatever part is.

So assuming you went through every step and it goes to the treatment machine, remember that-- no direct beam. No direct beam means-- usually treatment plan is pretty good. It's not going to have that, because we go through dosimetry and physics review-- make sure it's not-- but at treatment unit, especially when you treat 3D conformal.

And for example, this case-- here is the contouring of the pacemaker, and here is the field edge. It's only 1.5 centimeters from the field edge, and then you're going to

image that before you treat the patient. When you do the double exposure, you have to open the jaws, but even that 1 or 2 MU-- it could make a difference, right? So in that case, you need to take precaution to make sure your jaw is not opened to irradiate that pacemaker.

So then physician and care team-- they need to just take care of the interrogation or the check up of the pacemaker-- what kind of frequency. We have the guideline from other publications, but in our department, we leave that to the attending physician to decide, because depending on the manufacturer, or depending on lots of-- we know that. There are lots of challenges to get that pacemaker checked, but we want to make sure the patient is safe.

So then, we need to document that. If there is an interrogation happening for the pacemaker, we need to document that, and at least-- because, look at the manufacturer's recommendations-- at least should be after the completion of the treatment. And there could be other approaches that you can reduce the dose to the pacemaker, because if you go above 5 grey or whatever, and you're treating the same site as where the [INAUDIBLE] may be. But there is a risk about that, if there is an infection, possibly, or other things. But that's the physician-- they have to make the decision. They could a magnet technique-- basically that switches off certain functions of the pacemaker.

So just a summary-- I think I went through everything. The most important part-- you need to have standard policy and procedure in your department-- everybody follows that, so we don't have anything that falls through the cracks, and we miss that. So that's basically my message for this, and thank you for your attention, and I am open for questions.