# How are Cancer Protocols Created?

December 8, 2023

**Becca Battisfore:**

Welcome to the latest edition of the College of American Pathologists CAPcast. I'm Becca Battisfore, content specialist with the CAP. In this episode, Dr. Mary Edgerton will be talking with experts in cancer research, diagnosis and treatment. This month's Cancer Awareness Podcast is unique in that we won't be focusing on one specific cancer. Instead, our guests will be talking about the CAP's cancer protocols, how they're created and used, the difference between cancer protocols and electronic cancer protocols, and the future of synoptic reporting. Before we get into the questions, I'll have our guests introduce themselves. Dr. Edgerton, we'll start with you.

**Dr. Mary Edgerton:**

Thank you. I am Dr. Mary Edgerton. I'm a breast pathologist. I'm currently at the University of Nebraska Medical Center and I am the chair of the PERT Committee, which is responsible for the electronic cancer protocols. Dr. Harik.

**Dr. Lara Harik:**

Hi everyone. I'm Lara Harik. I'm a genital urinary pathologist at Emory University in Atlanta, Georgia, where I also serve as the medical director for the Clinical Laboratories Hospital Service Line. At the CAP, I am currently the vice chair of the Cancer Committee and I will be the incoming chair starting January 2024. So it's an honor really to be part of the cancer committee and also to be leading it moving forward in 2024.

**Dr. Stephen Edge:**

I'm Stephen Edge. I'm a surgical oncologist at Roswell Park Comprehensive Cancer Center in Buffalo, New York and the University of Buffalo. And I'm the past chair of the AJCC and the Commission on Cancer.

**Donna Gress:**

Hi, I'm Donna Gress and I'm the manager of Cancer Staging and Registry Operations at the AJCC, the American Joint Committee on Cancer. And I'm a former hospital cancer registrar.

**Dr. Veronica Klepeis:**

Hi, my name is Veronica Klepeis and I'm a pathologist at Massachusetts General Hospital in Boston where I sign out medical kidney. And at CAP, I am a member of the Pathology Electronic Reporting Committee or PERT. And during my time on PERT, I also had taken on additional roles as liaison between the PERT Committee and the CAP Cancer Committee. And more recently I've been vice chair of PERT. And starting in January, I'll be taking over as the chair of PERT.

**Eric Daley:**

Hi, I am Eric Daley. I am the Senior Clinical Product Manager for the Cancer Protocol and Data Standards Team at the College of American Pathologists. I oversee the implementation of the electronic cancer protocols into the vendor suites as well as work with the quality control team that works on implementing the electronic cancer protocols. I come from a background as being a certified pathologist assistant for about 12 years and had various roles in working with laboratory information systems.

**Becca Battisfore:**

Welcome and thank you all for joining the podcast. Dr. Edgerton, I'll let you take it from here.

**Dr. Mary Edgerton:**

Hi, now Dr. Lara Harik. Welcome. And just to level set for everyone, can you introduce us to the cancer protocols?

**Dr. Lara Harik:**

Thanks so much, Mary. It would be my pleasure. So the cancer protocols, it's best to think about them as a diagnostic and prognostic reporting tool that is created for pathologists by pathologists supported by the CAP. Their primary role is to make sure that the pathologist who is signing out the report submits and reports all of the important information that is needed in order to be able to take care of the patient. So the report is reviewed by the clinical team. We make sure that part of what is included in the report is what's the subtype of the patient's tumor, what is the grade, what are the margins? What is the stage? And that would really help the patients and their treating team to be able to understand more what the prognosis is for each patient and to put together a treatment plan for them.

**Dr. Mary Edgerton:**

I know the cancer committee is very responsive to the needs of pathologists. How do you receive requests for new protocols? And then what goes into deciding which protocols are created?

**Dr. Lara Harik:**

We really base it on end user need. So we are here to support a pathologists. If this is something that they're facing on a day-to-day basis, or it's common and there is no cancer protocol for it, we would like to hear from you. You can reach us at cancerprotocols@cap.org, but remember that in order for us to create a cancer protocol, you really have to have standardized data around the entity and the organ system. So the AJCC, the WHO should have, these are our golden standards that we follow. They should have histologic subtyping that is already developed for these organ systems as well as staging protocols that have been agreed upon to be used. And so we are flexible. We are more than happy to consider adding any new protocols. The way to do it, the process to do it is we identify an area of need and then we discuss it at the cancer committee. And then if it gets approved via the cancer committee, there is an appointed cancer committee expert member that starts drafting the protocol and then gets it vetted by a big team of national and international experts.

**Dr. Mary Edgerton:**

Who is involved in creating a protocol, and what is the process the committee goes through to create a new protocol?

**Dr. Lara Harik:**

That is a great question, Mary. Creating a protocol is really very intensive and it's a very well-thought-out process. The cancer committee appoint an expert member who usually has expertise and interest in the organ system that they're preparing the cancer protocol for. And once that cancer committee member is appointed, they start by looking at what are the golden standards? So what does the AJCC, what does the WHO say? And then through that we have a certain protocol that we follow, histologic subtype grading, et cetera. So using the skeleton that is provided for every single cancer protocol, you will create a protocol for the new entity or sometimes we just update the protocols to make sure that they are up-to-date.

So the cancer committee member is the one that starts the whole process and they submit a first draft to a well curated team of experts that includes PERT committee members as well as national, international experts. And we make sure to include people that come from different practices. So for example, academic practices as well as private practices or community-based practices. Everybody is included and by invitation, and it's usually people who have interest and expertise in these topics.

And then once the first team of experts vets the content of the first draft, let's call it the second draft, then the second draft would go to the house of delegates, especially if it's a new protocol that we're launching. So the house of delegates, the CAP's House of Delegate, we will have a meeting with them and we will go over the protocol, the changes, we'll get feedback. The feedback is open for about a month after the house of delegate meetings so that if people didn't have the chance to comment, they have plenty of time. And then we incorporate all of the feedback and suggestions and of course, making sure that it fits with the golden standards that we follow. And the final version is generated, which will also go through a QA process.

**Dr. Mary Edgerton:**

What standards and what data elements are included and what are your rules for including these? What kind of guidelines do you follow?

**Dr. Lara Harik:**

That is a really good question. I've been mentioning it and I probably should have mentioned it or explained a little bit more before. We base our guidelines on what is nationally, internationally recognized as standard setting organizations like the World Health Organization for the classification of tumors and the AJCC for the staging and their staging manual. Sometimes we also have other organizations that have been identified by the clinical team. For example, the FIGO system is also incorporated in the GYN protocols. And so we incorporate that as well because it's used by the clinical team to treat the patient. So remember that the cancer protocols are documents and synoptic worksheets that their primary purpose is for the treatment of the patient.

**Dr. Mary Edgerton:**

I guess if you say the primary purpose is the treatment of the patient, then you're speaking to being clinically actionable, all the clinically actionable items?

**Dr. Lara Harik:**

Yes, absolutely. It's clinically actionable or relevant because sometimes they don't have to take action on them, as you know, or we don't take action based on every diagnosis of breast cancer. But yes, they're clinically relevant for the prognosis of the patient, for the clinical team to be able to put together a therapeutic or a follow-up plan.

**Dr. Mary Edgerton:**

So what about those items of interest to researchers? If they're trying to collect data on reports, how do you treat those?

**Dr. Lara Harik:**

Yes, that's a really good question. Unfortunately, the cancer protocols are not for research purposes. So all of the questions that are included are really clinically relevant or actionable. So we don't really include any research questions that somebody is interested in. These are not meant to sort of survey and collect data and use it for research purposes. It's really meant to be used for clinical treatment and to detect the prognosis of the patient.

**Dr. Mary Edgerton:**

So I know that some of the items are considered required and some are optional. Is there, or can I say, what kind of judgment goes into distinguishing those?

**Dr. Lara Harik:**

The core elements, those are the required elements. We refer to them as core elements. Those are the ones that are necessary for the treatment of the patient. So that would include histologic subtype, margins if applicable. And even if they're not applicable, we have to say that they are not applicable in that situation. And of course, the staging of the tumors. There are two other categories of elements that are included. Some of them are conditionally required, and those are, or conditional core elements. And those are the elements that if they were present, then it's important for us to report them.

And then the third category is those that are optional elements and those you can tell that they're optional because they have a plus sign next to them. It's important to report them if you can, but they're not required. So they're basically elements that we're still learning more about, data is still being accrued. They may be important, and so therefore reporting them, you would be ahead of the ball if you report them. And then some of them are also not required maybe by everybody, but required based on certain institutions and certain therapeutic plans and clinical trials. And so that's why we put them in that category of optional because not everybody wants to report them, but at the same time, there are people who want to be able to report them and want to be able to use the synoptic worksheet or the cancer protocols in order to do that.

**Dr. Mary Edgerton:**

So a lot of the feedback I hear, and especially being a breast pathologist is that, "Oh, these protocols are so long and the breast one is so long." How do you respond to that?

**Dr. Lara Harik:**

I know, it's really a challenge. So the way that I respond to that is that, two things. The first one is rest assured that the cancer committee members are trying their hardest to give you the shortest protocol possible for you to be able to fill it up and be complete and comprehensive in terms of what needs to be included for the treatment of the patient, as well as making sure that your time is well spent. So that's the first thing. The second thing, Mary, I really think it's not really the experts in the cancer committee that are making the protocols long. It's basically all the knowledge and all the medical field advances that we have seen that really have put a burden on the pathologist in general because there's so much data that now is so clinically relevant. I remember the 1980s breast carcinoma used to be diagnosed as breast carcinoma period, next case. And then in the 1990s it started getting more complicated and then a lot of people quit at that point.

And then now in 2023, the breast protocols are so long, but everything is clinically relevant and is used to determine what the next steps for the patient is. We understand that some of them may feel like they're long, but it's really a balance between all the advances of the medical field, all the requirements on treating patients and determining their prognosis. And to be honest, I mean the synoptic format really makes it short in terms of, and sort of concise. So you have a question and then an answer. It would be a lot wordier if we had to put it in a paragraph format.

**Dr. Mary Edgerton:**

And how do the committee and staff partner to ensure the quality and completeness of a protocol once you've decided, okay, this is in, this is out, this is what it is. What's your quality procedure?

**Dr. Lara Harik:**

Yes. The CPDS is the cancer protocols and data standard committee. When the final draft is generated, we send it to our CPDS team who our CAP staff, and they subjected to a meticulous QA process that basically dissects this protocol and makes sure that every element is entered accurately, every element is up-to-date, there is no typographical errors. The references reference the right thing. And so it's really a very detailed process that takes up to eight weeks for each protocol. So this is not really a small process. It's a really very detailed, very meticulous process, and they touch base with the cancer committee author. And so it's basically, if they see something that they're not sure about they go back to the cancer committee author. So it's really, we cannot do the cancer protocols without the CPDS team. We really appreciate them being there and everything they contribute to the quality of these protocols.

**Dr. Mary Edgerton:**

What drives the cancer committee to consider updating a protocol once they're in production, and how do you keep up with the changes being made by the AJCC and the WHO?

**Dr. Lara Harik:**

Yeah, absolutely. This is an important question because the majority of our time is spent updating protocols and creating new protocols really is a small percentage of our tasks because there aren't really a lot of protocols to be created still. So we have around 100 plus protocols that include protocols that are for cancer resections, as well as protocols for biomarkers that we update on a frequent basis. So anytime that there is an update, either in the histologic subclassification via the World Health Organization or the AJCC staging, we issue a subsequent update to the respective protocol.

Our relationship with the WHO and AJCC is very close. We actually have liaisons in our committee that keep us up to date for all the new releases. We actually received the AJCC updates beforehand, and most of our authors are part of the WHO, so they're also privy to those drafts as well. And we start working on them as soon as we know that it's almost a final draft. So we start working on them and we update them so that they are current when they come out. So the pathologist is always reporting the most current histologic subclassification or staging for each tumor.

**Dr. Mary Edgerton:**

Let's hear from a surgical oncologist who's actually quite frequently the managing physician for a cancer patient's care. How do you use the cancer protocols and what was life before the cancer protocols?

**Dr. Stephen Edge:**

Cancer diagnosis and staging is becoming more and more complex. Having structured data in a pathology report, and as I'll talk about it in a minute, in other key reports, provides the information in a complex environment to the provider to quickly and accurately get the treatment information needed. In breast cancer staging and prostate and others now, we actually include many of these factors that people have to record on the CAP protocols directly into staging. So until the eighth edition of the AJCC staging breast cancer staging was simply T, N and M. But with the eighth edition, we specifically included HER2, ER, PR and grade as key elements to actually derive the stage group. We did this because without those information, anatomic staging in breast cancers bordering on irrelevant as a standalone. So having these elements in a structured manner both helps the provider and the registry and other programs have this information available in a readable and succinct manner. Before this and is still in places that don't use these templates, people just can't read the pathology reports. Everything's buried in the middle, and it's very, very difficult. It's the same thing with surgical reports.

**Dr. Mary Edgerton:**

That's a great way of putting it. Yes, there's an assembly of specimens and you're trying to put together, wait, what was that last specimen? And this one is a new margin. Where does it relate to the old margin? Now, I know that although the protocols are not research tools to research, say new data items, they can be used to identify patient cohorts for looking at patient outcomes and explore opportunities for quality improvement. What do you see the future of using the accumulation of all this data to look at outcomes?

**Dr. Stephen Edge:**

Data that are available in structured reports will increasingly be used for cancer management through decision support tools that will incorporate not only pathology data, but surgical data and radiology data into decision support tools that will function as guidelines or even pathways. Given the rapidly expanding knowledge about the personalized or individual characteristics of people's cancers and the various treatments that are available, without such decision support tools that will become almost impossible to stay current and to provide appropriate treatments. These tools are coming, many companies are working on them. Many pathways and guidelines programs are working with these, and it will only be by having structured elements that we're able to do it. Now, I think it's important to recognize that the pathology community has led medicine in establishing structured synoptic reporting. It's been what, more than 20 years now that you've been working on these protocols and have implemented them nationwide.

I mean, it's quite remarkable that the College of Surgeons required them for the Commission on Cancer programs, 15 years ago or more. And the recognition of the value of structured reporting has been slower in other disciplines. But over the last few years, the American College of Surgeons has specifically recognized the need for surgical reporting with synoptic reports and has started down that road to require synoptic operative reports. Similarly, there's efforts on by radiologists and members of the American College of Radiology to develop synoptic reporting for radiology reportings, but they're all 20 years behind your pathology community. So kudos to you. But this move to universal use of synoptic reporting will have major impacts on the quality of care because we're able to have structured information available for decision support tools as well as quality evaluation.

**Dr. Mary Edgerton:**

Well, thanks. I kind of see the move from narrative to discretized data as being analogous to the move from continuous measurement to discreet measurement. I mean, we're coming into the digital age now, so this synoptic reporting is akin to the digital age from the analog age. So actually I'd like to ask Ms. Gress now to comment about the relationship between CAP and the AJCC and not just how the AJCC is involved with the creation of cancer protocols and electronic cancer protocols, but also what that means to the registrar community.

**Donna Gress:**

We've really developed a good partnership between AJCC and CAP. The staff has worked well together. We reach out and have conversations all the time to really make sure things go well and on time. And AJCC is really involved in two different ways. I mean, we get involved when we update our content by going from eighth edition to version nine for a particular disease site. We reach out and we give CAP the new TNM definitions and the histology codes, the site codes, et cetera, that are going to play a role in that. But then we also give suggestions on how some of the terminology has changed a little bit or been clarified a little bit through the years and look at the protocols as a whole and how maybe we should structure them a little differently to make it easier for everyone to use and make sure the AJCC staging part is clear.

But as a registrar, it's been a huge bonus to the cancer registrars to have this structured data because it was always kind of difficult before to read between the lines and read all the information and make sure you're pulling out that one particular discreet piece of data that you needed.

**Dr. Mary Edgerton:**

So I want to point out that there's actually a couple of podcasts that are on our SoundCloud site that have been recorded with cancer registrars to talk about how they use this data. And if you can imagine reading a novel and then being asked specific questions, "So when did so-and-so enter the room?" Because that's very important to what happened subsequently and saying, "Well, I don't know. I don't remember. Maybe it was in chapter three." This puts it out there in a very succinct way. Now, from the cancer protocols themselves, we had the electronic cancer protocols. And so I want to bring in Dr. Klepeis who is going to be the incoming chair of to describe the electronic cancer protocols.

**Dr. Veronica Klepeis:**

Putting the clinical content aside first, and I'm probably stating the obvious here, but the electronic cancer protocols or the ECPs in the background are very different from the paper protocols in that there's quite a lot of metadata that's stored within the electronic protocols. So for example, for every single question and every single answer choice in the protocols, there's a unique code associated with each data element. There is some indication as to whether it's a required or conditionally part required or optional data element, and often there's even a designation as to what the text should look like at the time of data entry versus in the report, et cetera, et cetera. So we have all this metadata that's stored that helps with making it more efficient to enter the data, view the data, and then later on even search for the data. So from that respect in the background, they're very different.

In terms of the clinical content itself regarding the specific questions and answers that are asked in a protocol. Historically, there have been some differences between the paper version and the electronic version of the protocols. And a lot of those differences had to do with the fact that filling out a form electronically is very different from using a paper protocol to enter that same information. So when you're trying to capture the data in an electronic format, you want to put certain restrictions on the type of data that's getting entered, so you can capture it as a structured data element that is meaningful and useful downstream. So for example, if the pathologist and user is asked to enter in a size or a distance, you want to limit that to a number so that something can be done with it, that value later on. So calculate a stage, for example.

But if the pathologist can't enter a specific number, on paper, it's easy enough to enter whatever you want. But when you're entering that information electronic, then you need to provide additional answer choices to the end user so that they can enter something other than a number when that situation arises. So maybe I want to enter a number that is at least five centimeters, or maybe I can't enter a number or measurement and I want to just give it an explanation why. So in that sense, the electronic protocols are different from the paper protocols because they allow those specific additional answer choices so the end user doesn't get locked in. Another difference historically is that sometimes the sequence of the questions was different on paper versus electronic, and sometimes that had to do with the logic required to turn on or off certain sections in the electronic version. So when you compare them, they're similar, but there are these differences.

In the past when building an electronic protocol, it was the paper version that was created first and that would get built then after the paper version was created into an electronic version. So we weren't maybe restricting authors with a certain model or format, there was a standard format that was used. Sorry, that's not entirely true, but it was easier to deviate from the standard when starting with paper. So that has led to some differences, again, between the paper and electronic protocols. And not just between paper and electronic, but also between protocols for different organ systems created by different authors. So at some point, and I think this was really a great transformative point, I think in kind of the electronic protocols, is that CAP commissioned the development of a tool that's called the single source product or the SSP. And that tool has really kind of reversed the process. So now we actually start by building the protocols in the SSP tool electronically, and when the electronic version is completed, we automatically generate the paper protocol using the SSP tool.

So as a result, you don't really have any discrepancy now, or you shouldn't between what's on paper and what's entered electronically. So there's more consistency across the protocols that are built for different organs and systems and by different authors because now we're starting with that electronic version of the build, and we start with a generic model or template that gets customized for the clinical content for a particular organ. So it makes it more difficult to deviate from the model that you start with. And even though sometimes some deviation from the standard is necessary, there are those exceptions. But I think in the end, having the SSP tool and generating the paper protocols from starting with the ECP is good because it makes the experience of filling out a synoptic more efficient and consistent for the pathologist and then also for the primary care, if they're signing out diagnoses from multiple different organs and sites, they'll have the same experience whether they're using paper protocols or the ECPs.

**Dr. Mary Edgerton:**

So Dr. Edge and Ms. Grass, I just want to ask y'all real quick because in a moment we're going to go into how the cancer protocols evolve, and AJCC is an important partner there. How does AJCC decide it's going to change the way something is staged, which then affects how we change the protocols? Do you want to go first, Dr. Edge?

**Dr. Stephen Edge:**

Sure. The AJCC has expert committees, expert panels for each disease type. All of them have CAP representation, and those panels meet periodically to review whether there are changes necessary for staging. The cycle is about every five years. We're currently working on the ninth version of the AJJC. It's more of a rolling updates rather than the single book. I would say that in most cases, and Donna may correct me if I'm wrong, but in most cases the basic anatomic elements change very little from year to year. And certainly in breast cancer, what we are doing is looking at how to combine those elements in a way that gives stage groups, but for the pathologist, they will still be using the same elements. The one area in breast that we're particularly interested in is information on the response to neoadjuvant chemotherapy, and we've been talking with CAP and others about how we can capture more structured objective data on that, but that's beyond the scope of today's talk.

**Dr. Mary Edgerton:**

Okay. Wow. Yes. I was just going to ask you, do you see, just general quick, do you see protocols for neoadjuvant therapy as something that will be evolving or sections on neoadjuvant therapy in all organs?

**Dr. Stephen Edge:**

We think it's really critical. I mean, neoadjuvant therapy in breast cancer and across many diseases actually is being more widely used, and the response to therapy and the pathological response to therapy and how that can be quantitated, provides critical prognostic information and information to guide subsequent treatment. So yes, we are leaning very heavily towards our, so-called residual cancer burden or ICB index to be collected as a way to collect objective quantifiable information on the response to therapy. But again, I think that goes a little bit beyond today's podcast.

**Dr. Mary Edgerton:**

Okay. Well just real quick, Donna, is that going to affect the registrar community? It seems like there's going to be a whole new set of parameters to be included in cancer registries.

**Donna Gress:**

Yes, that is a lot of new data for cancer registrars, but obviously if we're trying to tell the patient's story and look at their prognosis, registrars are going to have to collect that additional information if it has a significant impact on their outcomes. So it's going to be critical and having the surgeons document it clearly so we know the information they saw during the operation, and then having the pathologist document those new data elements very clearly in either their paper or electronic protocol is going to be a huge help to the registrar so that they can easily identify and find that information. So we really have to be partners working together because everybody wants the data to analyze later on to evaluate patients and the new care they're getting. And so by working together, we can facilitate that.

**Dr. Mary Edgerton:**

So Lara, these are pretty complicated relationships with AJCC and WHO. Who are the gold standards in the staging and histologies. How do we keep up with them when they put out a new chapter? Does that just start us with an updating of a protocol right then and there? It seems like if it's all done in sequence, it's going to add on a lot of time.

**Dr. Lara Harik:**

Yeah, absolutely. We really pride ourselves on having a very close partnership with the World Health Organization as well as the AJCC. We have MOUs with both of them or a memorandum of understanding with both of them and a really very strong partnership where they share with us updates that are upcoming through the liaisons that we have. For example, Dr. Lokuhetty is one of the cancer committee members, and through those we are privy to have sort of a glimpse of what the updates will look like and we get a pre-proof copy of the changes that are going to happen.

And we usually like to wait until we have almost a final version or approved copy before we start incorporating the changes. And then of course, the release will not happen until we double check that all the data that is available in the cancer protocols match what is released by the WHO or AJCC. But yes, the process starts as soon as we know that there is an update upcoming. So yeah, we work very closely with them. They're great partners to have and we are very lucky to have this relationship with them.

**Dr. Mary Edgerton:**

Lara, do you want to say something about biomarkers before we go on into the vendor relationships and making the protocols?

**Dr. Lara Harik:**

As you know, Mary, the cancer committee generates the content of the cancer protocols, which includes both paper as well as electronic. And we do that in response to what the gap and need is on the clinical side. And so in addition to having and updating and creating and maintaining 100 cancer protocols of different tumor types, we also have started and really led by Dr. Joseph Khoury, who is currently the chair of the cancer committee. We started also moving towards where the current treatment is, into biomarkers. Now, I would like to mention that biomarkers come in different flavors. We have diagnostic biomarkers, we have prognostic biomarkers, we have therapeutic biomarkers. So there are many different types of biomarkers. Depending on the type of biomarker, we either incorporate them as part and parcel of the cancer protocol itself. For example, in the CNS diagnostic biomarkers and molecular alterations of the different tumor types are part of us being able to diagnose what the tumor is. And so they're incorporated in the cancer protocols that are assigned subspecialized to the CNS.

There are other biomarkers that are more prognostic or therapeutic. For example, in breast cancer, ER, PR and HER2/neu. These are therapeutic markers. They might have also a little bit of a prognostic element, but they are used mainly for determining the treatment of the patient. And I'm speaking to the choir here with the current audience. So these are carved out into a special biomarker template for breast that the cancer committee has created in order to help guide the treatment for the patients. As you know, this is the future, Mary. Biomarkers are an important part of what we do on a daily basis. They guide the treatment of the patients. I'm pretty sure Dr. Edge can chime in on this as well, whether in the breast or other elements. I think this is really the future of how we're going to be treating our patients and they're very important. And so that's why since they play an important role in the clinical treatment and diagnosis and prognosis, that's why the cancer committee has undertaken this as a big initiative that we are rolling out and expanding.

**Dr. Mary Edgerton:**

So one of the fascinating changes that I've seen over my career as a breast pathologist is as a resident, we measured detection of HER2/neu overexpression because it had prognostic information as to a more aggressive disease with a possibly poorer prognosis, whereas now the prognosis group is better because there's a treatment specifically that attaches itself to the Herceptin receptors and blocks their more aggressive behavior. So that's just to me, just wonderful evolution of medicine and the prognostic factor from bad to, it's really good because we can treat that.

**Dr. Lara Harik:**

Absolutely. I totally agree with you.

**Dr. Mary Edgerton:**

So we've talked about getting the information from the WHO and the AJCC and vetting it for clinical relevancy, and then Dr. Klepeis talked about how we develop the electronic cancer protocols and modeling. So now, how long does it take for the vendors to update their electronic cancer protocols once we release a new one?

**Eric Daley:**

Great question. Dr. Edgerton. Just like the CAP members, our vendors are held to the same constraints of the eight-month window post the web posting date. Most of the vendors follow this trend pretty much spot on. The vendor implementation team that I oversee have been running the metrics on this since 2019. When we started that metric, we saw about 107 days of average turnaround time for a vendor to get the protocol into their system. I'm happy to say that we've seen that number decrease over the years now that we've developed this vendor engagement team with the CAP. And last year in 2022, we saw the number go down from the 107 to 48, sorry, 58 days, which is about a 48% decrease in that number. So that's a really good turnaround time that we're seeing and really shows the vendor engagement actively working with the CAP and with our vendors.

**Dr. Mary Edgerton:**

Yeah, that's great. That means your team has really done some great work in that communication area. How do the vendors incorporate the ECPs into their platforms?

**Eric Daley:**

Yes, so all the vendors have the ability to go to our CAP file repository, which is our file share, where we house all the SDC native XML forms. Most of the vendors have a pretty strong parsing tool that allows them to parse it directly in their system. A few of the vendors have some post modifications they do after they parse it to get it into their system specifically. The big thing to recognize here though, is that a lot of the vendors do post QA processes afterwards, which I think definitely helps a lot with them getting the system in and ensuring that the file is correct.

**Dr. Mary Edgerton:**

So Eric, how do the vendors represent the ECPs in their user interfaces? Are they just all the same, looking exactly like the paper protocols?

**Eric Daley:**

Great question Dr. Edgerton. So I'd like to take this and put it in two perspectives. The first perspective is really the synoptic, which would be the output, and then the other perspective is the input, which would be the user interface. I start with the end first, the output, because a lot of our users like to know what it's going to look like when it's done. So looking at the synoptic output, most of the vendors use a single column style sheet. Some of the vendors have a little more robust processes and can do it in a tabular format, which is a double column output. The piece that I think a lot of our users are interested in is the customizations that occur.

There's about three main ones that a lot of the vendors support. One of them is moving items around, so changing the order in which you see the items. An example of this would be taking staging and moving to the top of your form. Some oncologists like to see that first, and most of the vendors do support that through print groups and other various means. Another customization is being able to add in customized answers and questions that you've added to the synoptic that weren't present from the CAP cancer protocol. And then the final one is taking multiple answers and putting them on the same line. So the example of that would be pTNM staging, putting the full stage in one line in the output. Now, I highly recommend to a lot of our users that the CAP Cancer Protocol website, it has a resource tool and it has in that resource tool, it has a synopsis output document that goes over what we allow and don't allow. Highly recommend people go through that and use that.

As Dr. Harik recommended before, there is a general email that's on the website that if you had any questions, feel free to reach out. My vendor implementation team's always there to help. Looking at the user interface and the input, all the vendors support a pretty broad format for their form filler. It's usually just a generalized question to next question to next question, user interface. Some vendors like Intuitive has some more robustness to it. Theirs is able to triangulate where a user is in the form as they're filling it out. So that does help. I think a lot of our users, some other vendors use voice recognition software, which I think also eases the user interface opportunity. So that's kind of where I would say that how the vendors represent the forms.

**Dr. Mary Edgerton:**

And then how do the users pull reports from their vendors. So we talk about the data being able to be reused because it's discretized, what's happening in that area?

**Eric Daley:**

Yeah, great question. So all the vendors maintain a lineage of the cancer protocols with the CTs of the specific items. Those can be queried using SQL or other business intelligence such as Clarity or Oracle. Intuitive's got a pretty cool tool, which is called Intuitive Insight. There's allows for discrete dashboards that individuals can pull at any time and then can modify, so they can see the results in different perceptions in different ways. They also allow for custom extractions that come out of that database as well. So most of the vendors do support, I mean all the vendors support that. It's more of a matter of, it's the ease to which you can pull it out. All of them have their different tools for doing that. I highly recommend our users be active in their user group meetings. Vendors all have user group meetings, they have user group forums. The more active you're on those, the more you're probably going to find out some of the customizations and different reportings you can do.

**Dr. Mary Edgerton:**

Well, that's great. So I'm going to call on each of you just to say what do you think is coming in the next couple of years and what's coming in five to 10 years? So I'm going to start with you, Dr. Harik.

**Dr. Lara Harik:**

The cancer committee will continue to maintain, update and create cancer protocols based on the needs of our patients as well as our pathologists. Our end users really. And our end users, as you all know, are the pathologists primarily, but really the clinical care team as well as the patient are at the heart of what we do. As the field progresses, we will continue to keep up with it. We will continue to update our cancer protocols such that they are providing the cutting edge as well as standard patient care to whatever time we're in. And as we move forward, this will incorporate whatever changes and improvements and advancements the cancer field as well as the medical field will impose on us. So that would be, you touched upon it, Mary, the neoadjuvant chemotherapy. We have started incorporating it in the cancer protocols. Our cancer committee members are super excited about it. We have incorporated in many of them. The biomarkers, we have created biomarker templates that will also help with prognostic as well as diagnostic and therapeutic guidelines.

And as we move forward, I think the field will continue to evolve and we really have a great structure to be able to evolve with it. I do see that as we embrace artificial intelligence and digital pathology, this could be something that we also have to keep an eye on and see how we can make use of it in cancer protocols and incorporate it as well when the time comes and when it becomes a reality for the practicing pathologist. Because for now, we are all looking at the slides and some of us are signing out the slides online, but artificial intelligence has a little bit more vetting to go through before it's embraced by everybody. So I think those are my thoughts.

**Dr. Mary Edgerton:**

Definitely. Definitely. Yes. And Dr. Edge did mention the decision support systems that use the discretized data. So Donna, would you like to add to that?

**Donna Gress:**

Well, I would like to see in the next few years, AJCC really try to find a way to electronically send a lot of our information to CAP instead of now just giving it to you in a PDF or some other type of document. Because we have all this electronic already as we're developing a lot of it to give to our electronic medical record vendors to show the physician. So ways to just modernize that. And as Eric has mentioned earlier, the more things are electronic, the last chance there is for that human error of trying to transfer or copy information and make mistakes. And so hopefully that will move forward with AJCC.

And to speak to the registrar side, this has come so far already for cancer registrars. I mean, I remember back in the day when you would call the pathology department because you were missing the tumor size or the total of nodes examined or things that weren't important for that disease site clinically. But registrars needed that because we have those same data fields across all sites just for consistency. And maybe there'll be ways that the data can then come into the cancer registry electronically or have coding in the background so that registrars aren't reading the report and then somehow miskeying or miscoding it in their cancer registry database. So making all this a lot more seamless to make it a little more error proof.

**Dr. Mary Edgerton:**

Oh, it would be great to see it come in near real time. And I know that that's one of the goals of the Childhood Cancer Data Initiative. So Veronica, how about you?

**Dr. Veronica Klepeis:**

So in the short term, I think I'd expect that we're, on the PERC Committee at least going to continue moving forward with making the protocols more efficient to enter in the information electronically. So we've done a lot of that work. I think continuing with decreasing the number of clicks, trying to build in more logic so that you can turn off certain sections when you don't need them or turn on certain sections. And being able to enter more data in a structured way, like the repeating sections that we introduced where if you want to enter structured data for multiple tumors, not just the largest one or the most significant one, making it easier to do that. I think a lot of that requires working with vendors more, which Eric was talking about. I think using our metadata in a way that prevents errors and makes it easier to catch those typos and things like that. It is kind of the direction that we should move in the short term.

But in the long term, I think my fantasy is where you would, like you were saying, Mary, you dictate what you see and then that pre-fills in a synoptic for you. I think we're a long way from that, but I think all these smaller steps like building the rules, doing the auto calculations, creating alerts, some of these are low hanging fruit that we can at least start implementing now to make it more efficient. And once we make it easier for pathologists, they won't feel as burdened and maybe they'll fill out that synoptic for the biopsy and not just the resection or fill out synoptics for non-cancer diagnoses as well. So trying to make it more efficient is I think where we should be focusing our effort.

**Dr. Mary Edgerton:**

That's great and important. And Eric, you're the closer here.

**Eric Daley:**

I'm the closer. Okay. Well, I guess in that case, I better say some thank-yous, but I just want to say thank you to all the panelists and to Mary for doing this podcast today. But yeah, I share the sentiments a lot of others who spoke up about this a few minutes ago. For me, in my opinion, I think short term is going to be a lot of integration. Integration, I'm more referring to, there is definitely some silos between biomarker information and what we get to the pathologist. I see biomarker integration being a huge part to sub classifying histological types moving forward. And I think that's going to be a huge part in the short term for us.

Another short-term project that I think a lot of us are involved in right now is the SNOMED integration. We've been working with Dr. Scott Campbell for some time, last year or so working with implementing the SNOMEDs into all the required electron cancer protocols. I see that work having a huge benefit moving forward and long-term really allowing for us to have an ontology for cancer diagnostics and more importantly, more of an interoperability internationally for cancer diagnostics. And I think when we move forward with that, I think like to what Dr. Klepeis is saying and some others have said about having more efficiency in filling forms, I think the logic is going to be another piece that comes in hand with that, because the more we can have this at our hands and fingertips, the better it's going to be moving forward.

**Dr. Mary Edgerton:**

And I have to say, it really was a huge step forward in having the templates and as Veronica said, beginning to have the electronic model drive what the paper model looked like in order to keep some consistency across all the organ systems. And this particularly helps people who are signing out different organ systems. I only sign out breasts, so it's the same to me all the time. But if I'm going from breast to colon to GYN to lung and everything is different and in a slightly different order, I have to say, "Okay, which one am I on now?" Whereas this way, my thought processes can utilize the same neural pathways, just train them and use them over and over again to answer these in sequence.

Well, thank you so much to everybody. That was great. I think a great opportunity for our listeners to understand how the protocols are developed. Many important issues, has to be clinically actionable, some uniformity across the organ systems as allowed, more user-friendly in the electronic protocols, the advancement of electronic transfer of data, the use of clinical decision support and our ever-ongoing relationship with our vendors and WHO and AJCC, keeping our arms linked together so that we can make this happen without anybody flying off the end. Thank you very much.

**Becca Battisfore:**

Thank you, Dr. Edgerton. And thank you to our guests for taking time out of your busy schedules to join us. Our goal for doing this Cancer Awareness series has been to show a more holistic view of the CAP's cancer protocols. So I'm excited to announce that this series will continue next year. So stay tuned for future episodes. And I want to thank you all for listening to this CAPcast. You can find links to the cancer protocols in the episode description. If you have questions about the protocols or have ideas for topics you'd like to see addressed in future episodes in this series, please email us at cancerprotocols@cap.org. And for more information about the CAP, visit cap.org.