

Paving the Way for APPs in Clinical Research



A Q&A with Christa Braun-Inglis

With more than 25 years of oncology nursing experience and more than 18 years as an oncology nurse practitioner, Christa Braun-Inglis, MS, APRN-Rx, FNP-BC, AOCNP, has a wealth of clinical expertise. The trajectory of her career has given Braun-Inglis a unique perspective on oncology care. For one thing, she practices in Hawaii, a state that consists of 1.42 million people spread out over eight islands and speaking more than 100 languages. In Hawaii, patients may reside on small rural islands that do not have a local cancer clinic or full-time oncologist. Thus, the availability of translators and airplanes is a common consideration Braun-Inglis must consider when treating her patients.

Braun-Inglis, a native of Buffalo, N.Y., earned her degree in nursing from the University of Hawai'i and returned five years later to earn her masters and become a nurse practitioner (NP). After graduating, she moved to California, where she worked in a cancer practice in San Francisco. There she met Randall A. Oyer, MD, (current president of the Association of Community Cancer Centers [ACCC]), who cultivated Braun-Inglis's interest in medical oncology as an advanced practice provider (APP).

She soon learned that she was blazing a new path in Hawaii as the only advanced oncology certified nurse practitioner in the entire state. Her clinical work with patients made her excel in matching the patients she knew so well with the trials she believed were most likely to benefit them.

Braun-Inglis believes that how APPs are onboarded when first joining a new cancer program or practice is crucial to their long-term success. "When I first came on, I was mentored by physicians and nurse practitioners to live up to my potential as a clinician," recalls Braun-Inglis.



University of Hawai'i Cancer Center.

When she left San Francisco and returned to Hawaii to join a large private medical oncology practice, Braun-Inglis used her training with Dr. Oyer to demonstrate to her new employer how her clinical skills could add value to the practice overall. She soon learned that she was blazing a new path in Hawaii as the only advanced oncology certified nurse practitioner in the entire state. Her clinical work with patients made her excel in matching the patients she knew so well with the trials she believed were most likely to benefit them. In time, she became recognized as a researcher in her own right.

In 2018, Braun-Inglis left full-time clinical oncology practice to become an NP/assistant researcher at the University of Hawai'i Cancer Center and a clinical faculty member at the University of Hawai'i School of Nursing and Dental Hygiene. "I have a hybrid position, in which I am a part-time clinician working with breast cancer patients and a part-time faculty member supporting clinical research," says Braun-Inglis.

Braun-Inglis knew that she was entering a line of work uncommon in her profession. "The common belief was that opening clinical research to APPs would take work away from physicians," she explains. Braun-Inglis would go on to prove that there is plenty of research to go around, and bringing more clinical trials into community cancer centers not only benefits patients, but also enables all clinicians to work at the top of their license.

In her current role, Braun-Inglis is positioned to help bring down the barriers that often stand in the way of other oncology APPs who want to assist with clinical research. "When I joined the University of Hawai'i, I wanted to get more APPs involved in research across the community," says Braun-Inglis. "I have mentored and helped train 10 oncology APPs in clinical research, and they are all now registered as non-physician investigators through the National Cancer Institute [NCI]. We recognize Hawaii's top accruals to trials each year, and in 2019 that honor went to an APP." Below, we ask Braun-Inglis for her insight into the role of APPs in clinical research.

Q. How did mentoring pave the way for your work on clinical trials?

A. I took the grounding that Dr. Oyer gave me in medical oncology and applied it to my work in Hawaii. One oncologist, Dr. Jonathan Cho, with whom I worked in my practice, was very engaged in clinical research. He worked with the NCI Community Oncology Research Program (NCORP) at the University of Hawai'i Cancer Center. NCORP brings cancer clinical trials and care delivery studies to people in local communities. Dr. Cho fostered my love of clinical research and instructed me in the conduct of clinical trials. Our patient base is very different from that of the majority of the country.

We became a team. He saw patients in consultation, and I saw them for chemotherapy counseling. We established a workflow in which we identified appropriate trials for our patients and recruited them. In identifying trials, I started working with the University of Hawai'i, and they began to invest in me and send me to research meetings.



Ko'olau Mountains in Windward, Oahu.



University of Hawai'i Cancer Center.

When I attended those meetings, I noticed that I was the only APP there. I typically saw medical oncologists, PhD researchers, clinical research nurses, clinical research professionals, and PhD nursing researchers—but they are all different from APPs. I wanted to know why there were no APPs there, since we are the ones who are typically working most directly with patients.

Q. Mentorship and coaching played important roles in shaping your career. How can other APPs get the training they need to support their interests?

A. When you are a new APP, it can be difficult to get experience on the job. There is only so much you can learn in school. The roles and responsibilities of an APP are very different from that of an RN (registered nurse). What you do day in and day out is not the same. You need to start thinking in a different way and make autonomous decisions. If you are not mentored appropriately by another experienced APP or oncologist, you end up limiting your abilities and scope and not living up to your full potential. Today, the skills of many APPs are wasted because they are not being mentored appropriately.

I've seen how important onboarding is to professional development. When new APPs walk into a busy clinic on their first day, many doctors assume that because they are APPs, they must

know what they are doing, and they do not take time to mentor them. They push work on new APPs without giving them direction. So when they make a mistake, they are dismissed as not knowing what they are doing. But the fact is that these professionals cannot take on new tasks without proper training. It becomes a game of *Survivor*; whoever manages to survive grows into their role over time. This situation is slowly improving, but in many programs and practices it is still sink or swim.

In oncology, APPs typically work in a blended model in which they see patients jointly with oncologists. Knowing what your oncologist wants and how he or she practices is important to your success. To set up new APPs to succeed, my recommendation is to pair them with a physician or other experienced APP who acts as a mentor or coach. Develop an onboarding plan for six months with clear measures to meet. Make sure that the mentor to whom you assign your APP has adequate time to dedicate to training.

Q. What are the barriers to APPs working in clinical research?

A. Primarily, it's the workload of APPs that hinders them from doing research. Poor workflow can also work against them. Even if a practice is very busy, if you have an efficient workflow, your APPs can be fully involved in research. APPs often say to me, "I



University of Hawai'i Cancer Center Faculty staff: Nate Ramos, Sasha Madenn, Shirley Higa, Diana Martin, Jenai Umetsu, Dr. Jami Fukui, Christa Braun-Inglis, Kate Bryant-Greenwood

have too many patients to do research.” Well, yes and no. It depends on how you set up your practice’s workflow.

When you have different silos for research and medical oncology departments, it’s virtually impossible to build an efficient workflow for conducting clinical trials. If a practice integrates patient treatment with clinical research and individual roles and responsibilities are clear to everyone, even a busy practice can host clinical trials.

To achieve a model in which APPs are active in conducting trials, it is very important to have a physician champion. I have had many champions over the years, and they have helped me establish my role as a clinical researcher. I think more APPs would be conducting clinical trials if this were the case for everyone.

Restrictions on the roles APPs can play in conducting clinical trials are another barrier. For example, the NCI does not permit APPs to prescribe drugs in clinical trials. Because that means APPs must track down physicians to sign prescriptions, processes can slow down and interfere with efficient workflow. This lessens the appeal of using APPs in clinical trials, since their scope of practice is limited.

For trials that do not involve medication—such as quality of life or care delivery studies—APPs can be very effective at accruing patients to trials (separate from an oncologist), given their knowledge of the patients they care for. However, because most com-

munity APPs are not engaged with the research community, they are often unaware of these trials.

When I joined the University of Hawai'i Cancer Center as an NP/assistant researcher in 2018, I wanted to get more APPs involved in oncology research across the community. I have worked to recruit the 10 oncology APPs in Hawaii to be registered as non-physician investigators through the NCI, which enables them to enroll patients in clinical trials. I mentor them, educate them, and help get them registered with the NCI.

Q. What roles should community cancer centers play in the conduct of clinical trials?

A. Community cancer centers treat about 85 percent of all cancer patients. When clinical trials are conducted solely in academic or research-specific settings, how generalizable are those results to the entire population? The patient populations of community cancer centers and large research institutions are very different. Their socioeconomic status is different, and their ethnicities vary. Conducting studies within local communities makes it much easier to apply findings to the populations most affected by cancer.

For example, if you give patients a dose of a drug found effective for people in a large city on the mainland, it may not be an appropriate dose for patients in Hawaii. A small Asian woman



Christa Braun-Inglis with a patient at Kapiolani Women's Cancer Center, a UHCC Consortium community practice site.

is not going to metabolize a drug in the same way as a group of Caucasian men in a clinical trial in New York City. In Hawaii, there are unique geographical and economic considerations that may pose transportation and financial challenges that patients on the mainland do not experience. When we conduct trials in our own communities, we better understand how different drugs affect a variety of people in ways that are not typically considered.

It is also vital that non-pharmaceutical trials that study quality of life and care delivery are conducted in local community cancer centers. As our patients live longer due to new drugs, quality of life and survivorship become bigger issues. We need these types of trials just as much as we need treatment trials.

I do think the movement of some trials to community cancer centers is accelerating, but we still have a long way to go. I would like to see more pharmaceutical industry and NCI-sponsored trials in local communities. Right now, it's difficult for community cancer centers to participate in pharma trials. They don't have

the infrastructure to launch trials as quickly as larger academic and tertiary cancer centers.

I would love to see NCORP grow. As the role of APPs expand in community cancer centers, it makes sense to allow us to participate in more oncology trials. Many times, APPs are the closest to patients, and they know their specific needs. They are uniquely suited to identify the patients most suited to participate in individual trials.

Q. What are the demographics and specific needs of the patients you serve?

A. I see everyone, from the affluent to the very poor. I even have one patient who is homeless right now. Honolulu is very metropolitan. Our patients are Caucasian, Asian, Pacific Islanders, and many mixed-race individuals from our local populations. I see patients, counsel them, order chemotherapy, do follow-up visits, and manage symptoms.



UHCC Director Dr. Randall Holcombe presents the UHCC Award for Most Non-Therapeutic Accruals to Oncology Clinical Trials to the first APP recipient, Ashley Springer, MS, APRN, AGPCNP-BC.

Hawaii is home to many different cultures and languages. For our patients who do not speak English, we often use in-person translators. However, at times that can be a barrier, depending on the culture of the person we are treating. For example, for certain Pacific Island cultures, there may be only male translators available. Sometimes that male-female dynamic between translator and patient can be uncomfortable for a patient who has breast cancer.

Nevertheless, as patients come into the clinic for treatment repeatedly, they become better and better at communicating in English. In addition, we often develop an unspoken language in which patients can indicate whether they are comfortable discussing something in front of a translator. In general, we do prefer in-person translators. When they are not available, we have a video conferencing system that provides translation services for our patients.

I have one patient who speaks a native language so rare that there is no translator available. Unless she comes in with her cousin, I cannot communicate with her. She is from Micronesia, a nation that consists of several islands in the Pacific. Hawaii is the closest state to Micronesia, so the people who live there often come here for treatment. Micronesians speak a variety of native languages. They make up probably 10 percent of our patients. Sometimes we get patients from very remote areas and there is no translator available.

It's a special population that we treat in Hawaii. We have a huge immigrant population in general. It's so diverse: 20 percent Caucasian, 20 percent native Hawaiian, 20 percent Filipino, 15 percent Japanese, 5 percent Chinese, 10 percent other Asian, 5 percent other Pacific Islander, and 5 percent other. There are so many mixed-race people here; I would say most of the people in Hawaii are of mixed race.

The multiple languages and cultures we encounter can create barriers to clinical trials. Perhaps the consent form or other paperwork is printed in English or Spanish, neither of which some of our patients speak. The language and cultural barriers we experience are not like those in other states. Our immigrants are very different from the majority of the country's immigrants.

Q. Does Hawaii's unique geography pose barriers to the delivery of cancer care?

A. Hawaii's unique geography and population can make it difficult to access healthcare here. In Honolulu, we have very good transportation resources, so patients can generally get to the treatment they need. But when you expand to the outer islands, it gets more difficult. We have approximately one million residents on Oahu and approximately 400,000 residents on the other islands that make up the state.

Every island outside of Oahu is considered rural. It's a challenge to retain oncologists on the outer islands; we have a lot of turnover. Patients there who need cancer care cannot always drive to their local clinic. If there is no one to treat them where they are, they must get on a plane.

We have oncologists who continually travel among the islands to provide care to patients where they live. In some practices, traveling to other islands a few days a week is the norm. At one of the practices at which I worked in Honolulu, we routinely flew to Hawaii Island to see patients there. That island did have a stable oncology clinic, but it's very difficult to keep oncologists long term, and we constantly struggled with that.

Q. Tell me about your research on the role of APPs in clinical trials.

A. When I joined the University of Hawai'i Cancer Center two years ago as nursing faculty supporting clinical research, I wanted to increase the involvement of APPs in clinical trials, especially in the community. (The University of Hawai'i Cancer Center does not have its own clinical space, so all of our practice is in the community.) I tried to research the role of APPs conducting research in community cancer centers, but I found nothing in the literature. One article addressed the potential role of NPs in research, but there was a lack of data on the topic that surprised me. So I began to develop a survey to determine if there were others like me and, if not, why?

I worked with ACCC to develop a survey for APPs and pharmacists, and I piloted it in Hawaii. I added pharmacists because they, too, can add value to clinical trials, as they are integral in reviewing protocols and medications. I gave the survey to 20 practitioners in Hawaii and then led a focus group to further refine the survey. I took it to the ACCC Clinical Affairs Committee and asked the members for feedback to ensure the survey reflected a national audience.

I then conducted a national pilot, surveying 28 NPs, physician assistants, and pharmacists to validate the survey on a national level. In January 2020, we (ACCC and Harborside) sent the final survey to more than 14,000 email addresses. Over a period of six weeks, we received more than 400 responses. We are now in the process of analyzing those data, and we have submitted an abstract to the American Society of Clinical Oncology. Ultimately, I hope to use my data and conclusions to advocate on behalf of oncology APPs and pharmacists who want to assist with clinical trials on the local level.

I particularly want to provide evidence that counters policies that prevent APPs from prescribing medications and thus fully participating in clinical trials. APPs cannot prescribe any drug in an NCI-sponsored clinical trial, whether they are primary treatment (e.g., chemotherapy) or supportive (e.g., anti-nausea) drugs. These tasks are the very essence of what oncologists rely on APPs to do.

APPs also cannot enroll patients in NCI trials that have medications as independent providers; we must enroll under a physician. This is also the case for non-treatment trials. While these trials may not be top of mind for physicians, they are for many




Iconic Diamond Head, Waikiki Beach, Honolulu, Oahu, Hawaii.

APPs, and they allow us to improve quality of life for our patients who are living longer. Good news, however: NCI is in the process of changing their guidelines. There are also barriers in pharmaceutical trials. Many clinical research protocols are not updated with an APP scope of practice.

Q. Can you share any preliminary results from your study?

A. Yes, we've found that approximately 90 percent of APPs believe there should be a role in clinical research for us, and more than 75 percent want to become more involved. More than 66 percent of the respondents practice in community cancer centers, where more research should be taking place. We identified several barriers to APPs playing a more active role in research, including under-representation on research committees, heavy workloads, and a general lack of knowledge about the trials that are out there. Only about 50 percent of respondents knew if they were part of an NCORP. Until these factors are addressed and APPs are embraced as partners in clinical research, I believe it is a huge miss for the community cancer centers.

On the plus side, I see more APPs becoming energized about this issue. Like me, they are identifying the barriers that exist and are addressing them. The bottom line is that little will change if APPs are not aware of trials and how they work. We should be aware, if for no other reason than we are the ones most familiar with the needs of individual patients, which makes us uniquely suited to match patients with the trials most likely to benefit them. APPs add value to patient care in so many ways, from managing symptoms, to coordinating care, to helping patients maintain a good quality of life. Research is an area in which they could also have a significant impact, ultimately resulting in better patient care. 

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