

Corramedical's Crow's Nest™ Biopsy Catchment System enables the Collection of Dislodged Tumor Cells that Would Otherwise be Discarded as Medical Waste – and Make Them Available for Molecular Testing



Dr. Alexander Arrow
CEO/Co-founder

Corramedical, Inc.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: *Dr. Arrow, what was the vision when you started Corramedical and what is your focus today?*

Dr. Arrow: The vision was to create tools to provide physicians the ability to make use of *all* the cellular resources they are already extracting from their patients, and in so doing provide tremendous benefits to solid tumor cancer patients who are undergoing core needle biopsy procedures. Can you believe that today, core needle biopsies are performed approximately 16,000 per day in the U.S., and in virtually every single one of those procedures, valuable tumor cells are simply thrown away with the disposable needle, rather than being washed off the needle and collected? This massive wasting of a precious biological resource (which is painfully extracted from patients) is even more surprising when you consider that only about 1/3 of cancer patients who undergo biopsies have molecular testing (either gene panels or genomic sequencing) performed on their tumor cells. Of those who don't **many are treated with chemotherapy while they could qualify for treatment with one of the new oncology drugs that affect only their tumor cells and not the rest of their body.** These so called "precision medicine" or "targeted therapy" drugs are modern miracles of science, but they are only available to those patients whose tumors have been sequenced. We estimate that as many as 1.8 million cancer patients per year in the U.S. receive chemotherapy, and suffer its many side effects (hair loss, nausea, mouth sores, bleeding, diarrhea, foot and hand numbness, and "chemo brain") when they could instead be treated with a drug that targets only their tumor. That's the problem that Corramedical was created to address.

Along the way, while we were developing the Crow's Nest, it turned out that the prospective hospital customers perceived other advantages of using it as well. Using it after every biopsy could mean that fewer patients would have to undergo 2nd biopsy procedures. Second biopsies are typically not reimbursed by insurers, so avoiding them can save a hospital the cost of the procedure, which can be \$6,000 when image guidance is included. Other health economic benefits include avoiding the cost of preparing formalin-fixed samples for molecular testing, which saves several hundred dollars per sample, plus the labor savings since laboratory technicians wouldn't have to spend the six hours that they typically do preparing those samples.

So our vision was based on a simple but surprising observation, that after a biopsy of a solid tumor, the cells that are on that needle from the tumor are typically lost because they are thrown away with the needle. But those dislodged tumor cells have tremendous diagnostic value because they come directly from the patient's tumor, and they haven't been damaged by formaldehyde – a huge advantage for molecular testing. We figured there ought to be a way to collect those cells and not waste them. After all, the patient is already enduring the invasive procedure of a biopsy. We really should make use of everything that was taken, shouldn't we. That is what our technology does, it is a simple mechanical way to capture those cells and thereby make them available for molecular testing or genomic sequencing.

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What we are focusing on today is the development and launch of our product that does that. We call it the Crow's Nest™ Biopsy Catchment System. We have fifteen hospitals that are engaged to start using it. We only recently listed and registered the device with the FDA, the non-sterile version. The sterile version will come out later this year.

The rise of precision medicine drugs has added urgency to what we're doing. Precision medicine began 27 years ago with the launch of a drug called Herceptin (trastuzumab) for breast cancer. Before Herceptin breast cancer patients had two treatment modalities: surgery and chemotherapy. With the advent of Herceptin, some breast cancer patients could avoid chemotherapy. It was a drug that went directly to the patient's tumor and did not affect all the cells of the rest of the body as chemotherapy does. But you only know if you are eligible for that if the mutation that caused the tumor is known. And you only know that if you have molecular testing or genomic sequencing -- which only about a third of patients that are biopsied get today. That's where we come in.

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CEOCFO: *Are you surprised that no one has thought about this before? Did it hit someone like a bolt of lightning one day? What was the process in researching if it was available somewhere?*

Dr. Arrow: People had thought of this concept before. In fact, our Chief Technology Officer and my co-founder, Dr. Wilfrido Mojica, thought we should be washing biopsy needles before throwing them away to collect the loose cells on them at least as far back as 2016. He called this the Cell Wash Technique, and published several articles about it. After "shouting from the rooftops" about the reasons for doing this for 5+ years and seeing nearly no adoption, he began to recognize the need, as did I when I met him, to create a simple-to-use device that would make it easy for every interventional radiologist who performs core needle biopsies to perform an instant needle wash and collect the cells in a 2nd specimen separate from the solid tissue core. This is a classic case of necessity being the mother of invention.

We know there are isolated cases of some hospitals and intervention radiology groups that wash their needles after biopsies, typically for cytology work. It is rare in the U.S. It is perceived as inconvenient because the clinician has to find a way to collect those cells and keep them separate from the tissue core, store them, preserve them and avoid damage from formaldehyde, and have them tracked along with the solid tissue specimen that comes from that same patient. It is possible to do that, but the fact is it is just not being done, so those cells are wasted.

We figured everybody should and could be doing this, if only there were a simple device that makes it foolproof and easy without the risk of mixing up the two solutions, then it could become widely adopted. Our device, the Crow's Nest, takes no more steps to use than a gauze pad does, because it performs the needle wash simultaneously with dislodging the solid tissue from the disposable needle.

CEOCFO: *Would you tell us about how the Crow's Nest works?*

Dr. Arrow: It consists of five interlocking plastic parts and two internal chambers, each with its own preloaded fluid solution. Immediately after a core needle biopsy, typically the needed is touched to a gauze pad on the table next to the patient, called the Telfa pad. That's the way the interventional radiologist transfers a piece of tissue that the needle just harvested. The tissue is dislodged from the needle by contact with the gauze pad. Then the gauze pad is folded up and placed into a jar of formalin, also called formaldehyde. That's sent to the pathology lab for processing, which is called Formalin Fixation and Paraffin Embedding or F.F.P.E., the acronym that all pathologists use for it. That is the standard of care after a core needle biopsy – approximately four million times a year in the US.

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Instead of that, if you use the Crow's Nest Biopsy Catchment System, you skip the Telfa pad. The radiologist instead takes that needle and inserts the tip into the upper chamber of the Crow's Nest, which is a closed bottom-funnel designed to fit any biopsy needle. It is pre-loaded with medical-grade saline. You simply swirl the needle in the saline, which dislodges the tissue in a way that is quicker and easier than wiping it on a Telfa pad. At the same time you are doing that you are doing that you are simultaneously performing a needle wash because the needle is being swirled in a liquid solution. Therefore, you are not only getting the solid tissue, you are also getting the loose cells -- something you do not get with the Telfa pad technique. Then you discard the needle and unscrew the Crow's Nest at the midpoint. It has a second place where it unscrews. You then simply pour the contents of the top half into the bottom half. That releases the saline containing that little piece of solid tissue plus all of those cells into a basket sieve. It is like a strainer with a very large pore size -- about 10 times the diameter of an epithelial cancer cell. The cells fall right through that basket and go into the bottom chamber, while the solid tissue core does not. The solid tissue is caught by the basket.

The user then lifts the basket and drops that into the formalin cup. So you have the standard solid tissue sample in formalin just as it would if you were using the Telfa pad. That is sent to the pathology lab just like normal. The bottom of the Crow's Nest is preloaded with liquid solution called Zymo cell lysis DNA/RNA preservation solution, at double the normal concentration. It lyses or bursts the cells and preserves their DNA. Surprisingly, the liquid specimen is stable for at least two years at room temperature. And the DNA is preserved in its pristine long-chain form. By contrast, formalin is damaging to DNA, whereas the Zymo solution is designed to preserve DNA. This makes it the ideal way to provide DNA for molecular testing because it is not fragmented and cross-linked.

"Countless medical devices available today have clinical advantages, but very few can say that they are creating a clinical and health economic advantage without taking anything else from the patient, but simply using something that has already been extracted and today is being thrown away. That is a unique reason why the Crow's Nest should be used. Tremendous clinical benefits and health economic benefits -- all from what today is going into medical waste." Dr. Alexander Arrow

CEOCFO: *Has that solution been around a long time; does everybody know what it is and that it works or is it something that you needed to develop along with your Crow's Nest?*

Dr. Arrow: Zymo DNA/RNA Shield® is something we source from its manufacturer, Zymo Research Corporation. It has been around for years. It is familiar to most pathologists, clinical lab technicians, and lab directors but not to interventional radiologists and not to oncologists. You could buy a bottle of it directly from Zymo Corporation and also buy some sterile medical grade saline, a pipette for pouring the saline over the needle, then use a receptacle to capture the cells and tissue, a strainer to separate the solid tissue from the loose cells, and a funnel to put the fluid with the cells into the Zymo. You'd also need a very small container to aliquot a 2.5 mL volume of Zymo so that you don't end up with an overly diluted DNA sample. Or you could simply use the Crow's Nest to do all of that. Instead of doing what amounts to a mini-chemistry experiment every time you perform a biopsy, we make it easy by putting this all into one simple product.

CEOCFO: *How are you storing your product and how do you keep track of samples without getting them mixed up?*

Dr. Arrow: Once the interventional radiologist has completed the process of using the Crow's Nest (called *biopsy catchment*), the new second specimen that is created can be used immediately for molecular testing such as genomic sequencing, or stored. If it is stored, it needs no refrigeration -- it is stable for at least two years at room temperature. During at any point in that time, the patient's oncologist may decide to request a particular gene panel to see if the patient has the mutation necessary to qualify for a clinical trial for a new oncology drug, or to see if the existing oncology drug will work on their tumor.

If it were not for the Crow's Nest, the way to do that would be to take a piece of that paraffin-embedded solid tissue and do the test on that, which takes two to three days, six hours of work from a lab technician, and the reagents that are used that are not cheap, for undoing the damage that the formalin did. Contrast that with what happens if you have one of our specimens. You can simply take this liquid specimen, which was never exposed to formalin, and send it directly from molecular testing. It gives you the additional option for every patient that has a biopsy, which you otherwise would not have.

With regard to the risk of mixing up samples, the collection tube has a standard area on its side for identifying information, to attach one of the adhesive stickers that is usually automatically generated with any lab test. It would carry the same label that the solid tissue block from that patient would have.

CEOCFO: *Do you ever see a time when this would be standard for everyone?*

Dr. Arrow: It should be standard after every core needle biopsy, because that would end the wasteful practice of throwing away valuable tumor cells as medical waste. That is our goal at Corramedical, to alert every clinician that does biopsies, or has the ability to get this technology introduced into their hospital's biopsy protocols, that this should be standard. It is a simple thing, very inexpensive, and a huge benefit to patients. There are as many as 1.8 million cancer patients in the US per year who are getting chemotherapy who don't need to because they have what is known as a *druggable* mutation. That means they could be getting one of these precision medical drugs like Herceptin that goes directly to their tumor and doesn't cause their hair to fall out and doesn't cause six months of severe diarrhea because it doesn't attack every cell in the body that is rapidly dividing like chemotherapy does. It instead goes only to the tumor cells that have that mutation. That should be standard for every solid tumor cancer patient. And the future in which that is the standard should come about as soon as possible.

CEOCFO: *How do you get from here to there; what is your plan?*

Dr. Arrow: Getting from here to there is our sales and marketing challenge. As with any company launching an important new medical technology product, our biggest challenge is getting the attention of busy clinicians, such as pathologists, intervention radiologists, and especially oncologists. There are three main physician groups that we interact with:

The first is pathologists, because they are the stewards of the tissue after biopsy and are in charge of keeping it for ten years after a biopsy and they face regulations from the College of American Pathology, to ensure that they keep their tissue for ten years.

The second group are the intervention radiologists and others who perform core needle biopsies, which includes endocrinologists and pulmonologists. They will be using our device, but they may only do that if told to do so by the oncologist because the oncologist is the one who cares about the information.

The oncologist is in charge of the patient's treatment. The oncologist doesn't want to have to make decisions on which drug to use based on incomplete information. They certainly don't want to tell the patient they have to get a second biopsy because they have run out of tissue after the first specimen is used up, which happens. That is called *tissue exhaustion* and it happens between 20% and 80% of the time after a core needle biopsy according to literature. That is another benefit, that you avoid the problem of tissue exhaustion.

CEOCFO: *How do you make this a standard of care?*

Dr. Arrow: We have to make pathologists aware that they don't have to witness sub-optimal care of your cancer patients. We have to make oncologists aware that they won't have to wait pathologists to decide which tissue block to use for NGS, so they save days off the time until their patient can commence drug treatment, and that the Crow's Nest enables RNA sequencing – so that fusion protein mutations can be detected. We have to make interventional radiologists aware of the few seconds it takes to use the device, and the many clinical benefits it brings for patients. And we have to make hospital administrators aware of the four ways that the routine use of the Crow's Nest after core needle biopsies saves the hospital money. It will also help us to get molecular testing labs on board with processing the 5 mL liquid specimens generated by the device.

CEOCFO: *What about insurers and organizations like the American Cancer Society?*

Dr. Arrow: We have multiple health economic benefits that insurers would care about and so would hospital administrators. We save hospitals cost by avoiding unreimbursed second biopsies. If a patient has to go back for a second biopsy because there wasn't enough tissue the first time, that is an unreimbursed second biopsy. That costs the hospital

\$6000 if it is an image guided biopsy which most biopsies are today. This is especially impactful in an in-patient capitated payment setting (DRG codes).

We also save money if a hospital has a lab by having fewer technician hours needed for tissue prep, and also by not having to use the reagent kits that are used today to prepare Fomalin-fixed samples for molecular testing. For those hospitals that send out their specimens for testing to third-party labs, we need to first demonstrate to the labs that it costs them less to process Crow's Nest liquid specimens that it does to process FFPE solid tissue specimens, so they can maintain their same margins while charging the hospital less per test. Those are three direct health economic benefits. There are indirect benefits that affect a hospital's bottom line and that the American Cancer Society would care about.

The most interesting one may be that patients could start therapy sooner. It takes one to three days between when the oncologist orders the test from when the sample is ready to be tested. Contrast that with the liquid specimen that our device creates which doesn't have to wait one to three days because you don't have to go through the tissue sample prep because it hasn't been exposed to Fomalin. That shaves one to three days off the time between when the original biopsy was ordered and when the treatment can start. The sooner the drug treatment can start, the better the patient's prognosis can be. That can save peoples' lives and affect the total burden of treating a patient.

CEOCFO: *Are you seeking funding, investments, or partnerships today?*

Dr. Arrow: We are fortunate that we have an over-subscribed Seed Round that we completed, so we have met our capital-raising goals and then some for 2025. We are seeking partnerships with clinical molecular testing lab companies.

CEOCFO: *When you are reaching oncologists directly or talking to the appropriate people, do they understand immediately and understand the benefits?*

Dr. Arrow: The response we most often hear is "Yes, of course this should be used." We also hear "I would prefer that every patient get sequenced." One told us: "If only I had a dollar for every time the pathologist told me there wasn't enough tissue..." Our main challenge is getting the clinician's attention. Once we have that and explain what we are doing, they are in favor of using it, especially oncologists.

From an oncologist's point of view, more information is better. When you are making a treatment decision, you want every patient who gets biopsied to get sequenced. From a pathologist's point of view, they feel they are often being caught in a "Catch-22" where their society regulatory requirements charge them with keeping adequate tissue in storage in the pathology department for ten-plus years, but they get requests from the oncologists to use up more of that tissue for additional tests, and they feel like they are caught in the middle. Pathologists don't want to witness suboptimal care for their patients either. Good pathologists feel that the patient is theirs as well. It gives them this additional liquid specimen that they can just hand over and say "Here, use this, you don't have to use up more of the solid tissue core. Just use the liquid specimen, it is even better."

CEOCFO: *How do you deal with some of the frustration of knowing you have something that could make such a difference and yet there are so many challenges to get it in use and wide acceptance?*

Dr. Arrow: That's how it is when launching any innovative new medical device, especially at a start-up. If we could just snap our fingers and make it instantly adopted, it wouldn't be the fun challenge that it is. We don't find that challenge to be frustrating. That is the nature of the game. We find peace from our knowledge that we are inevitably marching toward the day when every biopsied patient gets the benefits of molecular testing. Corramedical, Inc. is going to be an agent of change.

CEOCFO: *With so many new ideas in medicine, why should Crow's Nest, why should Corramedical stand out?*

Dr. Arrow: Countless medical devices available today have clinical advantages, but very few can say that they are creating a clinical and health economic advantage without taking anything else from the patient, but simply using something that has already been extracted and today is being thrown away. That is a unique reason why the Crow's Nest should be used. Tremendous clinical benefits and health economic benefits – all from what today is going into medical waste.