INTERVIEWEE: Dr. Alejandro Barbagelata
INTERVIEWER: Jessica Roseberry
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BARBAGELATA INTERVIEW NO. 1

JESSICA ROSEBERRY: This is Jessica Roseberry. I'm here with Dr. Alex [Alejandro]

Barbagelata. And, Sir, if you don't mind giving me your title, that would be wonderful. I usually

ask.

ALEJANDRO BARBAGELATA: Well, you know, I'm originally from Argentina. But now I

am UTMB. That's University of Texas, Medical Branch, as a faculty in the division of

cardiology with a rank of associate professor of medicine. And I am medical director of the

heart failure program down there.

ROSEBERRY: Right. Well, thank you very much, Sir, for agreeing to be interviewed today. I

appreciate that very much. I thought I might ask you how you first encountered the Duke

databank, what your first experiences with that were. (*sound of voices in background*)

BARBAGELATA: Well, that was in the old days when I was working in Argentina, as a faculty

in the Favaloro Foundation with the renowned surgeon Dr. [René] Favaloro. The story about

him, I mean, he was the one who first implemented coronary artery bypass in humans back in

'1967 when he was at the Cleveland Clinic. So after that, he became very famous and created a

large cardiovascular institution in South America, in Buenos Aires, Argentina. And I think it

was the largest institution in South America. I don't remember exactly the numbers, but it was

about 2,000 coronary bypasses per year and a number of PTCAs [percutaneous transluminal

coronary angioplasties] or stents. I mean, it was a very large—it still is—institution. He always had a dream to mimic the Duke model. He knew that Duke—I mean, that the famous databank where all the cardiovascular data , all the coronary bypasses since the beginning were recorded there and with long-term follow-up, and when new evidence came out from that information and that data could be used for better treatment on individual patients. So for him that was the way to go, I mean, the way to answer of question of what works best in cardiovascular decisions. And so the story was—at that time I was young faculty there.

ROSEBERRY: So this had reached Buenos Aires, the fame of this program? Or it was when he was in Cleveland that he had heard about this?

BARBAGELATA: When he was in Cleveland, he did the first coronary bypass in '67. Since then he became famous and then went back to Argentina, to Buenos Aires. And then he created a large cardiovascular institution down there.

ROSEBERRY: And did he hear about the Duke Databank when he was in Buenos Aires or when he was—?

BARBAGELATA: Well, I mean, he had a big interaction with the United States.

ROSEBERRY: I see.

BARBAGELATA: And he was—I mean, he was very connected with all the big centers worldwide. In fact when he did the first coronary bypass, at that time the Duke databank didn't exist. I mean, the next year I think it started ongoing, in '68 or so, or '69 or '70. I don't know exactly what is the start of the databank. But then all the information there, all whatever is new in cardiovascular disease was there. So for him that was amazing. So then he decided in 1993 to start a program with the databank at Duke. So he tried to mimic the model. So for that purpose I was sent to Duke as a fellow to start working on that. And for me that was an amazing

experience. It was really—you know, at that time I was a young faculty, and I think it was the second time I came to the United States. And to see all this new stuff, for me it was really amazing. But then an agreement was signed. I think I have a copy of that here.

ROSEBERRY: Oh, great.

BARBAGELATA: Well, I don't have a copy of the agreement. I have a lot of material, but I didn't bring it with me. But so one of the news at Duke were—I mean, tell the date that the agreement was signed. Well, the idea was to develop the Latino version of the Duke databank.

ROSEBERRY: Um-hmm. (*rumbling sound in background*)

BARBAGELATA: And to my knowledge that was the first international experience with the databank. I don't know whether there was any other. But it was the first international experience. So the agreement came out in the newspaper here in the United States. And in Argentina there was a lot of publicity about it and so on. It was really a challenge for me to start working on that. I came to Duke with my family, I mean, with my wife and my young children. I mean, I had one daughter at that time. So we started working in the development phase. So we have a lot of challenge. The first one was the language. I mean, we're Spanish-speakers. So we had to create a databank to implement in Buenos Aires in a Spanish-speaking institution. The second challenge was to interact, my interaction with the computer people. So we are talking about '92, '93, when the Internet was there, but nobody used it, nobody was really—I mean, today it's used daily. But at that time even in Argentina, it didn't exist yet. But then we had to create computerized stuff. So I had to interact with the computer people, which is a different language, too. And statisticians. So I worked quite—I mean, it was amazing for me to learn all this new stuff. And I think it took more than a year and a half to get the material ready, because we had to create—I mean, the Duke databank has a report generation, and the report generation had to be in Spanish

and in a wording that everybody understands. But not only, I mean, the medical language or the Spanish content of it; but also the medical words, because as everywhere, there are different ways to manage or to understand the definition of whatever disease we are taking care of. So we had to work a lot in getting the proper report generation for every single case or every single situation. And so it was a lot of work on that. So the day we finalized the development of that I think was back in '95. And then we did the implementation at the Favaloro Institute. I remember still the first patient collected. It was April '96. But the second challenge was communication between the two countries. As I say, the Internet wasn't established at that time, especially in Argentina. And so we had to work through the government in Argentina to create the ways to get good access to the Internet and then to generate all the communication protocols. Because it was kind of, if you want, I cannot say online but a very frequent interaction with Duke. So all the data coming out in the Favaloro databank was at Duke readily, too. So the computer people at Duke were taking care of the data management of that. So there was a two-way interaction all the time. And so it had to be created, all the proper technology for communications. But then another challenge was that—and again, today it's pretty usual to hear about "electronic medical records" —but in those days, you know, we had to make a kind of fusion between the system in the hospital at Favaloro with a new system, with the databank system, because many things had to be changed in the ongoing system at Favaloro. But the new system didn't answer all the needs for the institution. So it couldn't be replaced. So we had to create a kind of mixture. So we did a little bit different from the way it was done at Duke, the data-collection process. So I don't remember exactly what it was. But we put all the admission patients as a unique form; we used it as a medical record in some ways. But then every patient, once they went to the cath lab or to intervention or surgery, they had their own data-collection process. So there were a number of

people working on the databank on a daily basis. So the report generation we first tested in a number of patients. But then we implement it, huh? It works. And then at the beginning there had to be done a lot of correction and modification. But at the end of the day, (*booming noise in background*) then after two or three months, all the reports came out automatically from the computer. So all the referring physicians get their letters. So you make sure in that way to get quality of the data, to make the data qualified for them to do for research purposes. But then many other new challenges came out because—one of them I think it was to put together all the definitions of the information. Because the main idea was to have similar definitions that is used at Duke. So I mean, we can make then big pools of patients in the United States and Argentina and to compare which new treatment best works or to recall the prior experience to implement in newer patients. And so the definition got to be agreed between the both institutions, it took months to get agreement in every single variable on that. And then another challenge was that we started getting some—I mean, as the data came from the reports automatically, (*booming noise in background*) then we sent a letter to the referring physician. In the wording sometimes there were some misunderstandings. And so it was new stuff in Argentina. So sometimes we got some issues with the lawyers or even with patients about some data coming out. So we had to correct that. I mean, there were a lot of small stuff there. But finally we got that to be resolved. Another challenge was to see the data, I mean, that was the result of what we were doing. So complications, I mean—so whatever we do to the patients, there were a number of complications. So that also was very new down there because we are not used to the quality assurance stuff. And so that was very helpful in some ways because we learned how to apply according to the intrinsic risk of the patient, how to apply in the newer patients, that was really, really a good thing all that we learned on that. So I don't remember exactly the number of

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patients, because we included in the databank every single patient that came out with cardiovascular problems at Favaloro. But then only we include in the full record, I mean, patients undergoing catheterization like the way it's done at Duke. So from that, most of the diagnostic catheterizations were included, most of the interventions by catheter, most of the coronary—all kinds of surgeries were included. I don't remember the overall number of patients, but it was more than 15,000 or 20,000 patients involved in the databank.

ROSEBERRY: And did you follow them over time?

BARBAGELATA: No, we didn't. I mean, we did the in-hospital at that time. We didn't start with the long-term follow-up. So there were two years, two long—more than two years' data-collection process.

ROSEBERRY: Who was doing that collection?

BARBAGELATA: Well, I mean, they were an organized team.

ROSEBERRY: Was it physicians or—?

BARBAGELATA: I mean, it was a combination. I mean, it was data-entry personnel, there were some technicians, and also the physicians did their own part. So it was piece by piece getting all the data in the same day or the same—I mean, by the time the patient left the hospital, everything was ready. And then we would—we had to run the queries to make sure that the data was good and then interact with Duke, internationally. I mean, it was a huge experience. So then the story—I mean, we end using it in '98. At the end of '98 Argentina has a big economical crisis. And so very difficult times at that time. (*noises in background*) So finally we had to quite all the process. It was, I mean, quite expensive to maintain the process. And so those days it was very difficult to keep it up and running. So it was a very difficult time economically speaking. So even we have a paper to publish about that experience, because it was a great experience. We

never published that paper. I mean, we worked a lot of time on that paper, but we could never publish it. I think in the overall, I mean at the end—so there were more than four years we were working on that. I think it's a great thing to do. So to me—from this we came out with the first Latino version of the Duke databank, and I saw that it was proven to work. Also we need to learn many more things, we need to learn—I mean, I think there are some things necessary to do to finish the job. I mean, this is an unfinished job. Someone has to finish it at some point to get—I mean, this international databank model, I think someone has to finish it at some point. (*noises in background*) I think it is very, very important to have an ongoing combined data-collection process to readily have answers for all the cardiovascular problems that is really helpful for every single patient, to know what will best work for them.

ROSEBERRY: How is it useful?

BARBAGELATA: Well, I mean, to me in this context there are two different ways to read it. I mean, one is for how do you use it in the institution itself? So you have many different uses, not only from the administrative standpoint but also for quality assurance, but also for research purposes. So you combine all the—even for billing and all the administrative— (*this word difficult to understand in recording*). So you can combine and get information for all the aspects of the management that they receive. And so for the institution itself, I think it is a very valuable tool. But then if you do an international or a national interaction between other institutions, I think that is a new dimension, because you can get enough number of patients to see what's going on in the real world. So today we answer—most of the questions we answer through the well-designed, randomized clinical trials. But not many answers come out from there, because they are pretty expensive to test every single question. So you need to have other tools to answer the daily decision that every physician makes. (*noise in background*) And I think is the answer

for that, I mean, to generate a multi-centered clinical database or clinical databank like Duke, the Duke model is—. But that proves that—I mean, our experience proves that what Duke has done is unique. I mean, nobody could—I mean, we couldn't keep going. It's unique. I mean, it's a big effort. I think Duke gets that for I don't know how many years, and they're still ongoing. I think it's—I mean, I don't know who else can—. I hope somebody can do it in an interaction between institutions, even internationally. So I think they have that Latino version of the databank developed. So it may be at some point it'll be established again. I hope so.

ROSEBERRY: Do you know of any other international attempts to do this?

BARBAGELATA: Not to my knowledge. But I'm not really involved in it so much. It may be at Duke they know more. I think they were in interaction with Poland at some point in Europe. But those people in the databank must probably know better than me.

ROSEBERRY: Well, you mentioned, you know, there were some difficult times in Argentina, and the databank had to be shut down. Were the resources of the institute pretty heavily flowing into the upkeep of the databank? Did it need a lot of the Favaloro Institute's money?

BARBAGELATA: You know, to analyze those days was difficult, because, I mean, every single resource was important. And this—I mean, this was one of those resources that were really good to have it. But we did not generate resources for new things. So you had to choose which one to keep, which one to close. So not only the databank was stopped at that time. I mean, the Duke databank wasn't stopped at the time. So many other things were stopped. And you know the story, I mean Dr. Favaloro a few months later committed suicide. They were very, very hard days, both financially speaking, and it was very—the institution was huge in those days. So it was very difficult to maintain. So the story is a kind of a tragic story. So many things had to be closed, not only the databank; so had to make the decision which ones. And of course it was one

of those. I mean, the idea was great, and the experience was outstanding. (*noise in background*) But you know, when you have to choose whatever is needed to survive. I mean, then—so you had to make hard decisions. And it was one of the hardest I think for him because it was his dream; I mean, to have that in place and to have that model working. I mean, in fact, he couldn't accomplish the dream, because although it could be done over time, he couldn't get the real aspect of getting answers for new treatments for patients, never could have done that. I mean, we never could use really—I mean, we used it in many different ways. But couldn't get to the point to get answers for better treatments for patients. So that's one of the dreams that he had to stop.

ROSEBERRY: And how is the Favaloro Institute doing now?

BARBAGELATA: Now it's doing great. Now it's doing great. The institution recovered. So there is a school of medicine, have a big number of student fellows. The number of procedures are good again. They've again recovered in every aspect. His nephew is taking care of the— Roberto Favaloro is taking care of the institution at this point. I think they are doing a great job. They could make the institution to survive. Maybe at some point—I don't know. I mean, who knows? Very difficult to do this model again. I mean, maybe in some other area.

ROSEBERRY: Well, what did I not ask you that I should have asked you?

BARBAGELATA: Well, I think we talked [about] most of the experience. But I think this model at Duke is outstanding. I have a very close relationship with them. So I learn a lot. I mean, I could publish new stuff with them. We have big interactions. I learn from them a lot. I've learned a lot. So I'm going to keep doing it.

ROSEBERRY: Well, thank you very much, Sir. I appreciate talking with you.

BARBAGELATA: No, thank you very much for this.

(*end of interview*)

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