Interview with…
Dr. Aissatou Touré-Baldé, member of the Project Advisory Group (PAG)

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Doctor Touré-Baldé, can you tell me how you came to join the PAG, and why you think you were asked to become an adviser to the Meningitis Vaccine Project (MVP)?
I was invited to join the PAG in 2004 and I attended the first MVP meeting in Washington [*editor's note: a meeting of the clinical experts' panel in September 2004*]. But the first PAG meeting I went to as a member was the one that took place in December 2004 in Bamako. Initially, when I was asked to take part in this project, I was a bit surprised, as I'm not a meningitis specialist—in fact I'm a malaria specialist. I'm also an immunologist—not a bacteriologist. I said to myself: "What can I actually bring to the group?" But after thinking about it, I realized I did have experience in clinical trials because I was in charge of quality assurance during a phase Ib clinical trial in Burkina for a malaria candidate vaccine. Moreover, I'm very involved in ethics as I am a member of the Senegal National Ethics Committee. Consequently, I evaluate clinical projects, including vaccine projects, to ensure that they are carried out in the right conditions and that they follow "good clinical practice." I know there is a scientific framework to get acquainted with and ethics to respect, and I think that is why the people in charge of this project were interested in my career profile.

Why did you accept the invitation? I imagine that you already have a busy schedule at the Institut Pasteur…
Yes, especially as the work I do for the Ethics Committee is in addition to my normal work. The projects are quite big and they have to be examined in depth. Sometimes you have to go out and search for information so that you can provide a well-argued opinion. It does take up a lot of time, but I do feel useful and I feel that I am making a contribution both to the Ethics Committee in Senegal and to the MVP. The Senegal Ethics Committee is a relatively recent creation, although ethics committees in general are fairly recent. In Senegal, it really is a new thing so everything has to be set up from scratch. We need people from different backgrounds, but we also need people who are involved in research and who can see if the methodology is correct, as research that is not scientific cannot be ethical. I feel therefore that I can contribute to setting up a good ethics committee. As for serving on the MVP advising committee, I have to say that I really hesitated, because it meant even more work. I was really pushed to do it by people saying: "Listen, you really can contribute. We haven't got enough African experts; people who get involved and who, at an African level, have the different skills that we need." After all, meningitis is a disease that kills many young people in Africa every year. There is a lot of goodwill, people really want to move things forward, and we Africans must be part of the process. I took part in the first meeting to see if I really could make a contribution. At the end of the meeting, I realized that I was able to do what they were asking me to do. With my standpoint as a

member of an ethics committee and as an immunologist, I thought I could contribute something. Furthermore, with there being two meetings a year, I could attend them in my free time, in my holidays, as this work is not part of my professional role. In a way, I'm doing volunteer work but for the moment it is manageable.

Does that involve a lot of work?
Generally, our meetings take place over two days, and then travel takes up two more days at least, so in total the whole process takes four to five days. I also have to prepare for the meeting beforehand. Maybe in the future I will have less preparation to do, because I'm now up to speed on the project. Nevertheless, I did a lot of reading on meningitis and the existing vaccines in order to update my knowledge in those fields, and while that took some time I'm not really sure how much time that took.

It's your expertise that…
I don't think I could call myself an expert at all. I have got a wider view than people who work in very specialized areas. I work in two or three areas that are of interest to clinical trials, but I couldn't say that I'm an expert. Let's just say that I'm starting to gain experience in several areas, particularly in ethics, because you really have to ask questions and search around, since there are no ready-made answers in that area. Every case is different and the context must be taken into account while holding on to basic, universal values. We need to be aware of the fact that research is not a well-known practice in Africa, and it takes place in a very different economic and cultural environment. Care must be taken to protect people so that they can decide independently what they want to do while ensuring that they are not cut off from research. We must ensure that there is no injustice in this area. It would be very easy for injustice to happen, as people in our countries are generally very poor… the slightest thing can force someone to sign up to something that they would not have necessarily wanted to do.

During the PAG meeting, you mentioned an article that had appeared in a Senegalese newspaper. Can you tell me about that?
I am a member of the African committee of the EDCTP [*editor's note: European Developing Countries Clinical Trials Partnership*], which has a new vision. This program aims to finance clinical trials in order to fight the three diseases linked to poverty—tuberculosis, malaria, and HIV/AIDS. Right from the start, there was a close partnership between the African researchers and the project leaders through the Partnership Board, which was made up of African and European scientists, and through the African committee in charge of steering the project [*editor's note: Developing Countries Coordinating Committee or DCCC*]. Capacity-building is particularly important to this project. This ensures that trials are not just "parachuted in," but instead skills are truly reinforced. As we Africans were involved in the project right from the start, it seemed like a good idea to officially launch it in Dakar. I think that maybe the information did not get through, as an article was published in the press with the following headline: "Senegalese people being sold to be Europe's guinea pigs." Basically, the article was saying that we were doing clinical trials in our country because we do not have adequate ethical, regulatory, and legal frameworks and that tests, which couldn't be carried out in Europe, would be carried out in Senegal. We couldn't just let this sort of misinformation be published because this project is, in fact, the complete opposite of that. The project has involved Africans right from the start, and it follows quite a strict revision process from both an ethical and scientific point

of view. These projects can only take place if they are submitted to the ethics committees of the countries where the clinical research will take place. Furthermore, capacity building is a key part of the EDCTP! As the partnership's ethics spokesperson, I have often had to say that one of the essential aspects of this capacity building should be reinforcing the ethics committees of the different countries. This reinforcement is underway with several invitations to tender concerning the strengthening of the committees, the organization of ethics training seminars, and so on. I just couldn't let this article, which was based on completely erroneous information, be published, so I wrote to correct this in order to explain what the project was really all about.

Did the correction help to change public opinion?
The correction did influence some people's opinions (and I did receive messages about this) because it was published in the press and appeared on the Internet, but it was only accessible to people who read the papers and have Internet access. Having said that, in general, this sort of news story is taken up by the radio, for example. Researchers don't necessarily want to talk to the media because as a rule we stay in our laboratories and explaining the information clearly is not easy. However, I do think clear communication is vital if we want to promote research and be able to carry out clinical trials in our countries. People must understand what clinical trials mean and what the researchers' liabilities are to them. They have every right to refuse to take part, but people must be aware that trials are carried out to improve the health of the population in the long term. So, we really have to increase communication and explain what happens. Civil society needs to participate in a general debate so that we can reflect together on possible problems and find solutions.

Could the MVP have to face up to a similar scenario?
Could the same kind of thing happen to the MVP? I think that it could. It is a very sensitive subject. That's why I was saying that right from the start, we must bring everyone together—particularly the national authorities so that they are informed. We can't make people happy in spite of themselves. People must agree and be able to participate so they can then convey the information to the people living in the area where the trials will take place. It is highly likely that this sort of scenario will reoccur if no effort is made to supply information and communicate. That is why we must give a lot of thought to communication.

You have experience of clinical trials and ethics. In your opinion, how many people really understand what a clinical trial actually is? Does everyone understand that the new drug or vaccine might not be effective? Or that the dosage given is "being trialled"?
I'm not sure. I'm not well placed to say if people really understand or not. To answer that question, I think you would need an anthropologist who could really ask questions and carry out a survey to determine how well people have understood the trial.

What about power? Is it not also a question of power, in the sense that people feel they have to participate in clinical trials because the tribal leader or the head of the village has told them that it is important that they take part?
It is not just about power. It is partly about power but it isn't really the issue, as the leader does not necessarily force people into doing things. For us, it is more an issue of respect than power. Often, in our villages, the individual does not exist outside of the group and the community. Having said that, people can always say, "No, personally speaking, I don't

want to take part." But without claiming to be a social anthropologist, it seems to me that taking an individual decision must be much harder here than in Europe, and that is why we must be even more cautious and really explain things well. In the first instance, we have to go through the leader and the community, but we really have to insist on talking to people individually and trying to gain individual consent. I think that it is important to speak to people individually while also respecting the cultural environment and therefore speaking first to the community as a whole. This is an important point.

The first African clinical study will evaluate the vaccine in very young children. Can you tell us about the problems related to this?
Well, traditionally, we take the precaution of carrying out trials on adults and then we move on to young children. Yet, when the time comes to carry out efficacy tests on target groups, it is not always possible to test the vaccine first on adults. Having said that, this is not a brand new vaccine. Its design may be new, but there have already been vaccines of this type that have gone through the different phases including tolerance in adults, and through a well-defined process, so background information is available, and we think that the clinical study can be carried out. Furthermore, as the target group to be protected are young children, it is vital that we determine the right dosage to give them, and I think that we unfortunately can't avoid testing it on them. But this means that we have to be even more cautious than we normally are. Precautions have to be taken, and close monitoring must be carried out to prevent, or at least limit as much as possible, any adverse events.

What should MVP pay special attention to during the clinical trials and implementation of the project in Africa?
In my opinion, it is absolutely vital to have good communication, and it is also important that everyone knows that this project is all about health and, even more importantly, all about survival. Because in the event of an epidemic, it is not just a question of being well; it's all about surviving this disease. Once communication has been successfully carried out, I think that every time, the MVP should ensure that there is a working ethics committee in place that can review the study, and that the necessary approvals are obtained. After all, we are just advisors. MVP does have its own ethics committee, as does the WHO, but it is the country where the trials will take place which has the last word. Only people on the ground can know how things work in a country and what the environment is like. To me, those are the two main points to which the MVP needs to pay attention. In my opinion, the MVP must also ensure that there are sufficient resources so that monitoring can be carried out correctly and we can react very quickly in the event of serious adverse events. The resources need to be in place to ensure that the trial is done under optimum conditions. I think those are the three main points.

Your two daughters are twenty years old and you have a boy of twelve. Have they always understood and do they understand what you do? Do they understand why you are not always available?
Firstly, when my children were small I didn't have this level of responsibility or this pace of work. They are now quite grown up. The youngest one complains a bit that I'm not there as much for him as I was for his sisters (he is not as grown up as all that, and I think he still needs his mom). But my business trips are quite short. It is very tiring for me, but in general I try to cut the length of the time away in order to make them short round trips.

Very often, my trips last three, four, or a maximum of five days. I also try not to go on too many too close together.

Do you explain the situation to him?
Yes, but at the same time it isn't a black and white situation. I know that he must miss me when I'm not there, but at the same time he is quite proud to have a mom who works and takes the plane…

This isn't the first attempt to develop a conjugate vaccine — there were clinical trials in Africa during the 1990s. But it didn't work for whatever reason. What makes you think that this project can work?
I think this project stands a good chance of working because, first and foremost, from a scientific standpoint, it is based on a concept which has already been tested with the conjugate C vaccine in the U.K. So, we already know that, in principle, it works scientifically. Furthermore, we can actually make it. The technology was transferred over to a manufacturer in India that successfully developed a prototype. The project stands a good chance of working because everything was planned for early on. That's good. Right from the start, the price was negotiated so it would be accessible to countries that need it. Having set off with a long-term objective as well as this idea, the MVP stands more of a chance of succeeding than a vaccine that may be scientifically developed but is absolutely useless, as it is too expensive for people to buy. Having an all-encompassing approach, bringing together scientists and politicians from the countries where the vaccine will be used and tested, implementing a financial strategy to ensure that the vaccine is accessible and that scientific development takes place, is a truly global strategy, which means that the project stands a good chance of working, in my opinion.

What is the meningitis situation in Senegal?
There have been meningitis epidemics during which you hear that two or three children from the same family have died. It's really upsetting, and then there was also a case much closer to home, as the baby of the girl who helps in my home had meningitis. He suffered from very severe psychomotor sequelae—he couldn't walk and he couldn't even stand up until he was three years old. He finally died due to the sequelae. When you really think about it, you realize that we must do everything we can to ensure that children do not contract this disease, because even when they come through, there are often incapacitating and disabling aftereffects. Our countries have a lot of pathologies to deal with, and if we could eliminate one of them… well, that is also an important objective in my opinion.

Are there any local beliefs linked to meningitis in Senegal like there are in Burkina, for example, where it is associated with mangos?
Popular belief has it that diseases with symptoms of convulsions or delirium are never caused by bacteria or germs. It is always the evil spirits or something like that. I'm not too sure what people say about meningitis, but for malaria it is like that, and often, when people call it "the mango disease," it is because it breaks out during the mango season. Very often, instead of saying, "It's the dry, windy season, so there is a lot of transmission," people say, "It is linked to the mangos." I think that, in the majority of African countries, there are very often beliefs like that, which mean that we find it difficult to make people understand why children need to be vaccinated or taken to the health center when they are ill. For people, it has nothing to do with germs—it is something that needs to be treated

spiritually because there is an evil spirit. The lesson we need to learn if we really want to move things forward, is that having a drug or therapy is not enough, as a lot of communication is needed too. This aspect is very important, because it means that therapies are truly effective. If a drug is effective but isn't used because people don't accept it, it might as well have not been there in the first place.

What made you study pharmacy?
Firstly, you have to choose between maths and arts. I'm not typical because I like both. I started off studying Latin and Greek. It was during President Senghor's period in power; he was a very literary man and he encouraged classical studies. I started off studying classics, but somehow natural sciences did still interest me, so I left my classics course for the science course. Both my parents worked in medicine—my father was a doctor, and my mother a midwife—which did predispose me to being interested in a medical-type career. I didn't actually study medicine and I regretted this afterwards because I would have loved to have had contact with people and the opportunity to help them. I really like research because it is an intellectual challenge, but at the same time it is sometimes a bit abstract when you are working in a laboratory every day. The need to do something tangible has meant that I gradually started working for ethics committees. On a human level, you feel more useful. Of course, when I'm carrying out research in the laboratory, I'm also contributing but in a more distant way. I think that having contact and the chance to contribute something in a more tangible and human way is satisfying for me, and that is why I find it worthwhile to act as an adviser to the MVP during my free time.

Do you have any hobbies?
I am a big reader. Reading totally relaxes me. I read very eclectically—both detective novels and more weighty stuff. Reading helps me escape. I also like listening to music as it helps me recharge my batteries. I listen to music throughout the day; the type of music depends on what I'm doing. Apart from that, I have started doing sport. It's a way of getting rid of stress and tiredness because I work a lot on the computer which makes me very tense and tired, and for me it is one of the best ways of just emptying my mind… You know, meetings are often very intense. You come out really tired but after the meeting you have a rest. Of course, when you are at home, after the meeting, you have other things to do. The problem that all women have, however, is that we have to work and run the house and organize family gatherings. Families are often pretty big in Africa.

The vaccine won't be manufactured in Africa. Is this a problem? Are you disappointed about this?
No, not really because it's a partnership. Maybe in the future, it would be good if vaccines were manufactured here. It might be part of our capacity-building effort. If one day we manage to manufacture things in Africa under optimum safety and quality conditions, I'd say "great." But we are not going to wait for things to reach that stage to develop a vaccine. There is an urgent need right now, so we go straight to the places with the necessary quality and skills. I don't think it is disappointing. It all goes hand in hand with capacity building. Economics also play a role, because you need to have resources in order to be able to manufacture a vaccine in ideal conditions. However, I feel that the laboratory and serology work should be done in Africa, because it would be relatively simple to set up by training people and providing them with the resources they need.

Is there anything else that you'd like to add?
Promoting research in Africa must go hand in hand with promoting ethics committees and capacity building. I can't help thinking about what happened twenty or thirty years ago, for example in America, where ethnic minorities were approached to take part in trials that are now unfortunately used as case studies in ethics classes. As the partners with whom we work with have their own ethics committees, I don't think we will get to that stage. But we must also be careful not to get into that kind of scenario, in the sense that our notion of individual freedom here in Africa has not yet reached the European level. Although I am a researcher and I really want to promote research, it is important to do things ethically in the same conditions as elsewhere.

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