

**Microbicides 2006:  
Official Opening of the Scientific Session  
April 24, 2006**

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[START RECORDING]

**AYANDA NTSALUBA:** Good morning, ladies and gentlemen.

[Audience: Good morning.] I know Cape Town is a bit down in terms of the weather, but we shouldn't be down like the weather, as conferences such as these. We would like to begin our proceedings this morning and let me first acknowledge the presence of the distinguished guests and our VIPs this morning as we begin this very important conference here in Cape Town. I want to welcome and acknowledge the minister of health of South Africa, who is going to be our keynote speaker this morning, Dr. Tshabalala-Msimang. There will be presented later the minister of science and technology, Minister Mosibudi Mangena is also here. Two ministers from our sister countries, Uganda and Rwanda, are here and they are also welcome. We also acknowledge the assistant director general for family and community health of the world health organization, [Inaudible] is here. The embassies for health, those are members of the executive council for health in the provinces of South Africa, there are two at the moment from Quazalunatal [misspelled?] where I come from, and from the western Cape where I also work sometimes, and we also have the three chairs of this conference that will actually be introduced to you at a later stage and the conference organizers, other distinguished guests that we haven't been able to acknowledge, they are

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also acknowledged and researchers from all over the world, and participants at conference.

Ladies and gentlemen, this is a very important conference as you well know, and we as the South African government are very pleased to be part of this conference and to ensure that it is opened in a manner that is befitting of a conference of this nature with high level government participation. My name is Ayanda Ntsaluba and I am director general of health in this country, South Africa.

As you know, director general is a title that is just general. There is nothing specific about it. It is just general, so I will direct you generally this morning [laughter] and there will be other people that will do the specifics on my behalf, but you must know that they are under my general guidance and direction. [Laughter] Without much ado, I would like to actually call upon one of those people that I am directing generally, the Western Cape embassy for health, Mr. [Inaudible] Ace to come forward to welcome us to this wonderful city of Cape Town, and I will tell you more about it later because I hear that you have already experienced it in one way or the other, Embassy Ace.

[Applause]

**EMBASSY ACE:** Thank you very much to all, and ladies and gentleman that is the director general of the department of health of the republic of South Africa, and thank you to

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him, welcoming us here as well this morning. We did extend a welcome to all of you yesterday evening. I think it was an outstanding evening, well organized and well planned. We don't see all 1,270 delegates here yet. I am sure they enjoyed some of the good things in Cape Town and in the Western Cape last night. We had an excellent program and again, from my side, I really hope that you will enjoy the day and the next days to come in the Western Cape, in Cape Town, and enjoy the fairest Cape. As we said, and D.G. referred to that, the weather is not 100-percent but as I said yesterday, maybe towards Wednesday it will be better. It is also a way of keeping the delegates here and participating in the discussions here this morning. Minister, it is also very good to see you here this morning. Thank you very much for being with us. The director general already welcomed everybody. I also would like to acknowledge my colleague from [Inaudible] Inn, embassy from [Inaudible] Inn, so good morning to you as well. It is also my pleasure then to move on to our first speaker, and that is Minister Mangena. He is a minister that will address us now, Minister of Science and Technology of the Republic of South Africa and that is since 29<sup>th</sup> April, 2004. He attained MAC degree in applied mathematics from the University of South Africa, joined South African students organization, and elected into the students represented of council of the University of

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Zululand, 1971 already. He has also achieved some of the Botswana region of black conscience movements over Zambia, and that was in 1981. He became deputy minister of education. I think that is a very good combination you see there of the Republic of South Africa and that was between 2001 and the 27<sup>th</sup> April, 2004, and of course then he was appointed minister of science and technology. He is author of three books; the first was *On Your Own*, a quest for true humanity, and a twin word. Ladies and gentlemen, it is really my pleasure to welcome our minister of science and technology to the stage to address us, please minister.

[Applause]

**MOSIBUDI MANGENA:** Thank you program director. I am suffering from a rather severe bout of flu, and I am hoping that I won't start coughing violently while still here. Of course, the minister of health didn't know about it until now, otherwise she would have ordered me to bed without.

Honorable minister of health, ministers, and MEC's present here, directors general, heads of departments, and city officials, chairpersons of the organizing committee of this conference, representatives for the [Inaudible] organizations, academics, and members of civil society, distinguished guests, ladies and gentlemen, congratulations on having this landmark conference in South Africa and on the African continent. Recent statistics on HIV and AIDS suggest

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that increasing numbers of people are being infected with the HIV virus. We know from studies in southern Africa that the reported levels of condom usage are low and the women unfortunately, due to socioeconomic and other reasons, cannot always ensure that safe sex is practiced. Therefore, the need to find alternative methods of preventing sexually transmitted HIV infections cannot be sufficiently overemphasized. Microbicides offer an important opportunity to give couples, but particularly women, more discretion and control in reducing the transmission of the virus. What is also important is the bidirectional effect of a successful microbicide that could prevent male to female and female to male HIV acquisition. South Africa occupies an intermediate position between least developed and developed countries. We also have a very energetic biotechnology and life sciences community. Given that microbicides research is on the department of health's comprehensive plan for addressing the HIV pandemic, the Dept. of Science and Technology is a committed partner in ensuring that in hands levels of research and development of microbicides takes top priority. To this end, my department has agreed to be one of the sponsors of this conference, and created two conference awards for the best young woman scientist and to the best young African scientist, which will be announced at the end of the conference. In addition, my department organized a

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strategic planning session with prominent South African researchers in this field. The result was the development of a road map for microbicide research in South Africa. Based on identified research areas in biomedical research, a consortium of researchers are currently busy developing research proposals intended to enhance South Africa's capabilities in bringing together a larger number of diverse researchers. We have scientists that are able to conduct world class research and enhance their good scientific practice by creating an enabling environment for technology transfer that can lead to the development of newer classes of products and services. Several advanced clinical trials have been or are currently being conducted by the South African Medical Research Council in Durban that a productive health and HIV research unit in Johannesburg, the University of Cape Town and in Popo, and at the Africa Center. With one exception, all products that are currently in advanced stages of research are being evaluated in South Africa.

It is likely that the efficacy of a candidate microbicide will be known as early as 2008. However, huge disparities in access to resources and levels of development between developed and developing countries often leads to tensions and frustrations. We do not yet have a system in place, at least in South Africa, to accelerate product manufacturing and availability on a larger scale. If we are

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to ensure that HIV prevention options are available worldwide, and especially on the African continent, accelerated production, distribution, and access would need to be in place among communities where the research took place. So, one of the solutions is to encourage, facilitate, or ensure that the transfer of technology also cares in the developing world. The biotechnology industry in South Africa is growing rapidly at present. The growth is in all related fields, and that is biochemistry, genetics, molecular biology, microbiology, genetic engineering and biotechnology, exceeded 46-percent between 2002 and 2004. This bears testimony to South Africa's commitment to strengthening biotechnology. South Africa has a keen interest in the intellectual property development and protection, and technology transfer with a view to developing our competitiveness globally. However, the effective protection and generous licensing of intellectual property can also be used to advance public good agendas related to food security, health, and public safety. Assuming that an economy of a region or county has the capacity to secure intellectual property efficiently, these options and choices remain open, and this for example is the approach adopted in securing patents related to HIV and AIDS vaccine development in the South African Vaccine Initiative. The core motive is not profit but publish it to achieve low cost with high reach and

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efficacy. I believe that if the technology holder and the technology recipients see mutual advantages in their relationship, then technology transfer would fundamentally be about the negotiation of agreements, which constitutes the transfer of [inaudible] role players but more than this, their relationship is about the general sharing of knowledge based on the assumption that this will lead to the acceleration of development and testing phases and a sounder sharing of benefits, including benefits to those who use the products. This is a matter of political will and the commitment of resources globally and locally at levels that would accelerate the development of safe and efficacious microbicides. This is not a two year task. Good signs link to sound ethical trials, public information, and low cost delivery are all part of a complex mix we have to mobilize to achieve success. The prevailing theme of this conference should be partnership. Some people still cling to the quaint allusion that the strict separation of mandates is possible [inaudible] in a quintile state. However, experiences from innovation systems are convincing enough to show that it is the in direction and interinstitutional flow that galvanize true creativity and innovation. This conference, with four defined themes, namely basic science, clinical trials, social science, and community perspectives, provides a comprehensive insight on every aspect of HIV prevention efforts, that is be

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it a virus in a test tube, animal models, or humans. This broad spectrum underscores the need for multidiscipline area research involving numerous partnerships locally, nationally, and internationally. I salute everyone present here for devoting your time to this worthy cause. I have no doubt that you are on the right course to discovering a relevant HIV prevention method soon. This discovery would come as a huge boost for South Africa and the continent if the first efficacious product was tested and made available on our continent. Ladies and gentlemen, thank you very much for your attention. [Applause]

**AYANDA NTSALUBA:** Thank you very much, Minister Mosibudi Mangena for those words. Just to say that the minister of science and technology, he used to also be under my direction generally when he was a deputy minister of education, and so he is used to being directed by me generally. [Laughter] I also want to acknowledge the presence of the deputy minister of health, who has joined us. Welcome, Deputy Minister. I also would like to acknowledge the president of the medical research council sitting in front here who is also part of the VIPs that are here. Thank you very much. The embassy for the Western Cape is going to come back and do the honor of introducing the minister of health. Just to say that I am really pleased that the minister is able to be with us this morning, because he is

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actually supposed to be leaving later today for Mosco because he is joining the G8 meeting there to address at their invitation that conference, and coming from there she is also joining the African union conference in Abuta, so it's a very time in South Africa as we prepare for the world health assembly and for UNGAS, and in a typical South African way, we do these things in very vibrant methods and so on, so welcome to South Africa. Welcome to the vibrancy! And you will see it is by the mountain that overlooks you, it is a very vibrant mountain. The lion's head actually says I am watching, so please be careful. Embassy, over to you.

**EMBASSY ACE:** Thank you director general. You didn't refer to devil's peak that is here as well. Good morning also to our deputy minister that is here. Ladies and gentlemen, it is a pleasure to introduce to you Dr. Manto Tshabalala-Msimang. She is the minister of health of the republic of South Africa since June 1999. She obtained a B.A. degree at the University of Fort Hare. First Leningrad Medical Institute in Russia, she obtained her medical studies and qualifications, department of obstetrics and gynecology at Dar es Salaam Medical School in Tanzania, a master's degree in public health, University of Antwerpen in Belgium, and then she worked as a medical superintendent, responsible for ten satellite clinics at [Inaudible] Hospital in Botswana. She was also deputy secretary in charge of human

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resource development and deployment for the African national congress, Dept. of Health Tanzania and Zambia, 1979-90. She had several positions in the national progressive primary health care network, especially in Durban, from '91 to '94. She was also on the national executive A&C Children in Tanzania, and she was also the coordinator of the A&C health plan for South Africa. She is a former chairperson of the portfolio committee on health. She is also, and maybe you didn't know this, deputy administer of justice of the Republic of South Africa, 1996 through June 1999. She also had very research in other publications; one of those that I am going to mention is the research around A&C woman's league submission to the [Inaudible] committee on abortion and sterilization. Ladies and gentlemen, she was an exile for 28 years and currently she is leading the department on a massive public health awareness campaign that is aimed at really looking at healthy lifestyles in South Africa. She is a devoted wife, married to Mr. Mendi Msimang, who is also the treasury general of the A&C in South Africa. She has got two daughters and I think this is very important, three grandchildren, and I've seen this already, she really enjoys them and they enjoy her of course. It is a real pleasure to invite you to the stage, Honorable Minister, Doctor Minister Manto Tshabalala-Msimang. Thank you. [Applause]

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**MANTO TSHABALALA-MSIMANG:** Good morning, everybody. Good morning. [Audience: "Good morning."] Surely you must be livelier. This is such an important conference; especially if I am introduced as [inaudible] I am not available. [Laughter] Good morning, everybody, and program director at the embassy, thank you very much for those kind words of introduction. I would like in particular to recognize my colleagues, administer of science and technology, recognize my other two colleagues, the minister of health, ministers from Uganda, and Rwanda, my own quality deputy administer of health in the country, the AGG that [inaudible], my very good friend or so, Joy Phumaphi, we have known each other for a very long time, I would like to also say thank you very much to the chairpersons and members of the conference organizing committee for having asked me to come and say a few words this morning, and recognize in particular [Inaudible] and I think [Inaudible] will also be chairing the session after this. Thank you very much. We have had really very vibrant interactions with them when we are trying to clarify a few things, particularly with regards to the work that has been done in this country. [Inaudible] general, who is the program director, has [inaudible] and city officials of course, I thought the embassy from northwest was here as well, but I am not quite sure and my very dear daughter, the embassy for health from [Inaudible],

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she calls me mama so I can call her my daughter, thank you very much all of you, representatives of various multinational organizations, researchers and academics, members of civil society, distinguished guests, ladies and gentlemen, my president [Inaudible], all protocol [inaudible] just in case you've forgotten anybody, but of course I can't forget to recognize the president of the MFC in the country, so thank you very much for allowing me to be part of this meeting. I must regret that I can't stay right through because, as you have heard, I have to proceed to Moscow tomorrow evening so there are some preparations that I have to do for my departure. It's a very important meeting, I think, because it so happens that I happen to be the only African minister who has been invited to the G8 ministers of health meeting in Moscow, so our voice in Africa must be heard in Moscow. I would like to invite our visitors, particularly those from abroad, to take time to see a little more of our country in between and after this conference. I am also sure South Africa has a lot to offer. I can guarantee you that once you have seen South Africa and its people you will definitely visit us once again.

It appears that the conference on microbicides has come to our country. This year, South Africa observes 50<sup>th</sup> anniversary of the heroic action of women who marched on the union building in Pretoria during the height of the apartheid

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in 1956 thus placing women of our country in the forefront of a struggle for national liberation. We have made great progress in the department of women since the advent of democracy in 1994. In addition to improve the representation of women in decision making positions, there has been a great deal of effort to ensure that policies and programs, particularly of government, are assertive to the needs and aspirations of the women of our country.

We begin this conference with the hope that it will contribute to protecting and promoting the interests of women to empower them to take charge of their sexual and reproductive health. I trust that this conference will discuss microbicides, not only as products used to prevent infections amongst women, but also as tools for promoting women's health and empowering women. We believe that a development in marketing of effective microbicides will have a great impact on the wellbeing of women and consequently on their children. The invention of effective microbicides will ensure that the health of women in relation to sexually transmitted infections will no longer depend on their ability to negotiate safer sex and the balance of power in their relationships with men. As you know, while condoms remain an effective intervention in the prevention of sexually transmitted infections and unwanted pregnancies, their effective use remains very much dependent on the cooperation

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of men. Therefore microbicides represent empowerment for many women who need to protect themselves from the risks associated with unprotected sex.

You may be aware that African ministers of health declared 2006 as the year of accelerated prevention of HIV and AIDS at last year's WHO AFRO meeting in Maputo, while aware that intensifying interventions includes the challenge of looking for additional tools that can be added to the existing set of interventions to deal with the spread of HIV infection and the impact of AIDS. It is encouraging that this conference is forecast on research that seeks to strengthen prevention of infections including prevention of HIV infection, while aware that several potential microbicides have been tested globally, with five out of six products that are in advanced stages being tested in our country South Africa and elsewhere in the world. I understand that our mechanism of action is different from [Inaudible], nine otherwise referred to as N9. I am particularly pleased that there will be a dialog around the N9 microbicides during this conference. When I first heard about the results of the study N9 conducted in South Africa, I must say I was very concerned. One of the issues that this conference therefore needs to address is ethical recruitment of candidates for clinical trials in a community that is poor, providing financial compensation could prove to be

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pervasive incentives. As we know, the poor may become desperate to receive these incentives despite risks; therefore, informed consent becomes even more critical in this context. We need to ensure that research participants receive the necessary care for the management of conditions that they may be exposed to. One of the key issues that this conference needs to address is what happens when there are complications from a clinical trial. From an ethical point of view, we need to answer how do we compensate patients who suffer such complications and ensure that they have adequate insurance? The type of insurance that is available for research participants in developed countries should be extended for participants in developing countries. It is unethical that participants in one multi-country study should have unequal levels of protection. I would like you as researchers skilled in the areas of clinical trials and ethics to make necessary recommendations to these complex issues. As a health minister, it is my responsibility to make sure that the health of the citizens of our country, South Africa, particularly women, is not adversely affected in the process of research, that has affect on the lessons learned in the inland study and planned future studies, with these lessons in mind to avoid similar problems. We are all aware of the possibility of the outcome of a clinical trial may not be as positive as expected during the planning stage.

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It is of critical importance that we ensure that our methods, procedures, and planning are impeccable. I hope that during this conference we will discuss methods and procedures that will make clinical trials safer for those who participate in them.

I am informed that your deliberations over the next three days will focus only on clinical science, but you also extensively discuss issues around informed choice, community responses, and participation in clinical trials. South Africa provides a unique environment for research. The former advantaged areas of our country have good infrastructure, skilled researchers and well equipped research institutions comparable to many developed countries while the rest of the population is affected by the burden of disease common to many developing countries, particularly in Sahara and Africa. These features of our country have attracted many international institutions to choose South Africa as a site for research. As you know, increasing with such activity, competition, and an attractive research environment may sometimes result in ethical practices. As we utilize the opportunities presented by this [inaudible] country, we need to ensure that we protect human rights, particularly of research participants as unchanged in our constitution and the national health act of this country. This should become standard practice in all developing

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countries I would think. With respect to the South African context, the national act provides for the establishment of the national research ethics council, which must among other things, register and audit health research ethics committees, set knowns and standards for conducting health on humans and animals, including norms and standards for conducting clinical trials and adjudicate complaints and institute disciplinary action if ethics have been contravened. The establishment of the ethics council is one of the most important steps we have taken to maintain ethical conduct and research and protect the rights of research participants in our country.

Let me take this opportunity to also announce that in line with the international requirement for the registration of clinical trials, South Africa has recently established a national clinic trial register. The register will not only inform the Dept. of Health of ongoing trials, but will also enable trial participants to obtain more informed information about trials. I have spent through some of the topics of presentation. I must say it is clear that although the developing countries are used as testing sites, research capacity to conduct these trials does not exist in many of these countries. It has ensured that the issue of strengthening research capacity in Africa and other developing countries is fully addressed. African scientists

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must more and more become the leads of researchers and studies conducted on Africans in Africa. We have to develop a strong research culture and problems that are of greatest concern for Africans. I am encouraged to learn that for the first time in the history of this conference there is a track dedicated to advocacy and community issues. We need to hear the voices of the people we are researching and their families. Let us not forget our commitment to improve the lives of ordinary people and this will guide us in our deliberations during this conference. I look forward to participating in some of the sessions at least today, and hearing the outcomes of the conference. Let us strive to ensure that this conference contributes significantly to improving health, including reproductive health of our populations. Delegates, ladies and gentlemen, it is a pleasure for me to declare this conference open. Thank you very much for your attention. [Applause]

**AYANDA NTSALUBA:** Thank you very much minister for those words and for declaring the conference open, so the conference is now open. It is really now open. I would like to take this opportunity as I said at the beginning on behalf of the government of South Africa to thank the organizers of this conference and the international participants for choosing South Africa as the site of a very important conference like this one, and of course I want to thank the

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speakers that have actually come forward today to open the proceedings of the conference. I still need to do a bit of directing general before I ask Melanie to come in for one or two announcements as we move towards the conclusion of this particular part of the conference session. I told you that all of you are under my direction generally in this conference at this point in time.

There are people that will direct you specifically, but I will do it generally. The first direction generally from the point of your government is that indeed as I said, please enjoy your stay in Cape Town, but you must also recall that you are here to discuss a virus and how to deal with it, and all the defenses that you need to take care of, and like any other societies that also have a viruses of a social nature, so please also protect yourself first from this particular virus as you mingle and jazz up and do all sorts of things. [Laughter] Please remember that you are actually the ambassadors of that prevention, and make sure that you do prevent, and I look forward to a time when I am going to be able to say after talking about abstention and so on, use a condom, or a microbicide, and a microbicide. [Applause] I am looking forward to that time when I can also say that, but while we are actually still working on it, incidentally those boxes that you are receiving, please use them with caution because they are just sampling for scientific studies, they

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are not yet saying that we are "the thing" because I have seen some of them are circulating and I heard some colleague saying "yeah!" Please be careful. But apart from dealing with that, can you also deal with the social viruses that you might have, they are not so many because we are in Cape Town. It is a very lovely, friendly city, but there are just basic things that we need to look into, such as for example let's not carry our cameras or cell phones, you know, in a manner that actually invites attention from some viruses.

[Laughter] And all these other things that are supposed to help, and just take the basic precautions, preferably if you are walking around.

As I say, you can walk anytime of the night here, as long as you actually know that you are looking after yourself, both inside the hotel from the other things that might be happening at the virus level [laughter] and outside the hotel from the social matters that are actually involved. So, that is directing generally and please when the director general speaks, everybody listens including ministers, you saw that. [Laughter] And so I hope you would actually take that very, very seriously. Of course as I also alluded to, please enjoy the Western Cape. Please enjoy Cape Town. Actually it is very easy to enjoy Cape Town. When you get lost, just look at the mountain and you can reorientate yourself, because everything is actually relative to the

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mountain. So, if you get lost, just look at the mountain and the devil's peak on the one side and the lion's head on the other will tell you where you are and which way you need to go, and once you have done that, you are actually very safe. The devil is looking after you [laughter] and the lion is looking, depending on which side you want to be on, who you want to actually be looked after. So, please enjoy.

Finally can I call upon, I think, Melanie, to make some announcements before I hand over the chair to the chairs of the next session, and after Melanie I would like to actually thank a couple of people as is procedure and protocol. Melanie?

**FEMALE SPEAKER (MELANIE):** Ladies and gentlemen, before we begin with the plenary session I have a few program announcements. Firstly, we apologize for a printing error on page 16 of your program, as well as on the screen to my right. Minister Mangena's name was incorrectly spelled. Minister, we apologize.

Secondly, we have a change to our plenary speakers this morning. Ms. Zoe Bakoko Bakoru will deliver her plenary address this morning as opposed to Wednesday morning, and Zvavahera Mike Chirenje, who was due to speak this morning, has now moved to Tuesday. Thank you.

**AYANDA NTSALUBA:** I thank you very much, Melanie. We do understand the problem with the spelling. I thought you

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were going to say where the spelling was wrong. I think the "u" should be the "i" at the end of the first of the name. But of course South Africans, too, many of them, so don't worry about the spelling because South Africans, too, don't know how to pronounce that surname. The Zulus will simply say "Mangen." [Laughter] And they have pronounced it, so I am not going to try it myself to actually say how it is pronounced, unless I actually pronounce it wrongly, because I am also a very typical Zulu, so for me that is "Mangena." But actually that is "Mangen." You can see the richness of the language is as rich as everything else that is rich in this country. We are rich in leadership. You saw the two leaders that were speaking here. We are rich in everything.

[END RECORDING]

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