



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

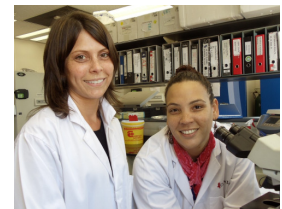
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998-1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

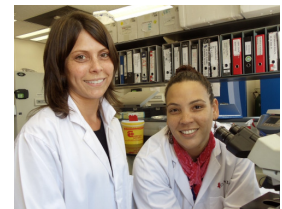
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998–1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

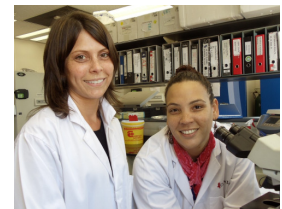
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998–1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral

load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>





Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

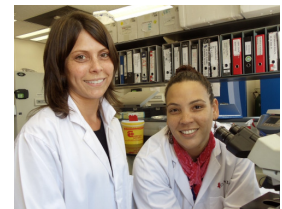
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998-1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

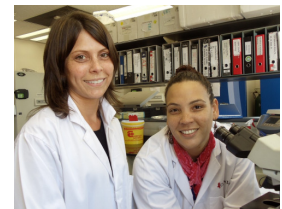
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998–1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

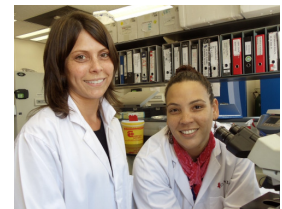
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998-1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

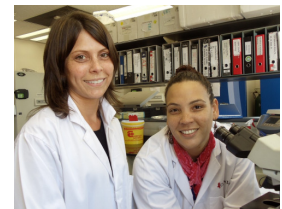
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013



29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998–1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter

Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

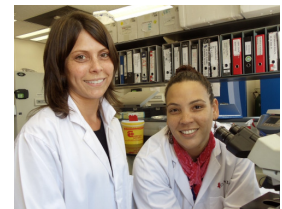
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998–1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

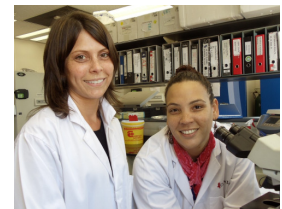
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

- 29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2
- 30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>
- 31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033
- 32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998-1999.
- 33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

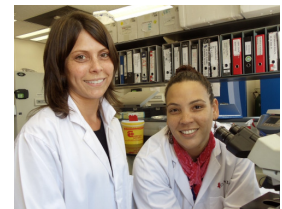
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

- 29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2
- 30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>
- 31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033
- 32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998-1999.
- 33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

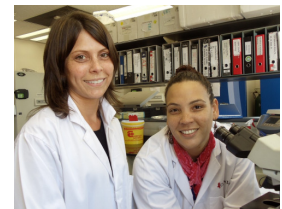
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998–1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

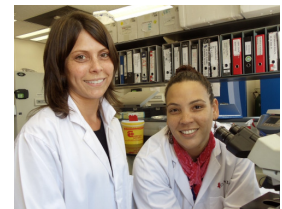
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998–1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

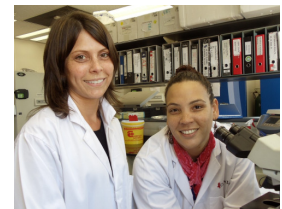
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998-1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

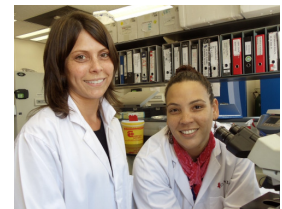
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998-1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

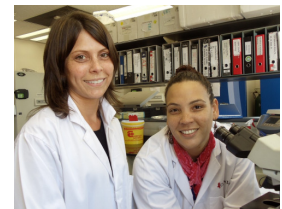
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998–1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

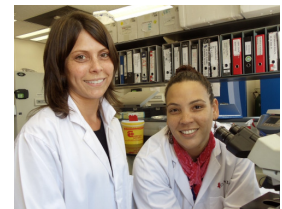
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998-1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

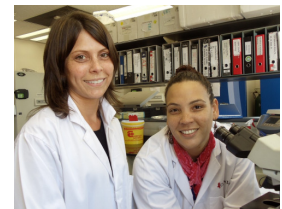
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998-1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

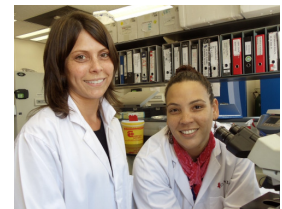
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

- 29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2
- 30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>
- 31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033
- 32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998-1999.
- 33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

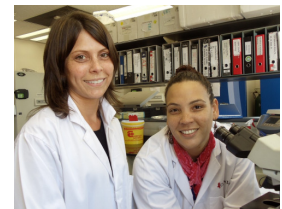
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013



29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998-1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter

Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org



In this issue...

Our feature story covers the results of a CAPRISA 004 sub-study, which showed that tenofovir 1% gel carries no safety concerns in Hepatitis B virus carriers

On page two, leading researchers address KZN community representatives to give their perspective, post SA AIDS, on getting to zero

Turn to page 3 to see which CAPRISA research fellow reached the Mail and Guardian's top 200 list of interesting and amazing Young South Africans



CONTACT DETAILS

CAPRISA
Doris Duke Medical Research
Institute (DDMRI), 2nd Floor
University of KwaZulu-Natal
Private Bag X7, Congella 4013
South Africa

T: +27-31-260 4555

F: +27-31-260 4566

E-mail: caprisa@ukzn.ac.za

www.caprisa.org.za

[caprisaofficial](https://www.facebook.com/caprisaofficial)

Tenofovir gel safe in Hepatitis B virus carriers

New safety data on Tenofovir gel from CAPRISA 004 sub-study

The results of a sub-study from the CAPRISA 004 tenofovir gel trial showed that no safety concerns were encountered from intermittent use of tenofovir 1% gel by women who were chronic Hepatitis B virus (HBV) carriers, or who developed acute HBV infection while using tenofovir 1% gel as prophylaxis against HIV.

Tenofovir disoproxil fumarate (the oral formulation of tenofovir) is already licensed for the treatment of both HIV and HBV. However, oral tenofovir has been associated with the relapse of hepatitis symptoms when the drug is interrupted or withdrawn.

If tenofovir gel becomes a licensed product for HIV-prevention in women, it is possible that it could be used either intentionally or unintentionally by HBV carriers.

Since it was not known whether hepatic flares may also apply to the gel formulation of tenofovir and since HBV carriers are often excluded from antiretroviral-based microbicide trials, this study sought to establish the safety of tenofovir gel use in a HBV patient group participating the CAPRISA 004 tenofovir gel trial.

At enrolment, 34 women were identified as being HBV carriers and 22 women acquired HBV infections during follow-up.

On average the gel was used 5.9 times per

month by women with HBV infection.

There was no increase in the number of HBV-associated hepatic flares in women using tenofovir 1% gel. Additionally, there was no impact on viral



load suppression in women with HBV infection.

Overall, the number of liver-related adverse events in women in the tenofovir gel and the placebo gel groups was similar, regardless of HBV status.

Previous data from the CAPRISA 004 trial showed that intermittent tenofovir 1% gel caused no significant renal, haematological, genital or bone effects.

These results are reassuring for women who have chronic HBV infection. They need not be excluded if and when tenofovir gel is made widely available for HIV prevention in women.

Reference:

Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS. Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial.

Antiviral Research 2013

<http://dx.doi.org/10.1016/j.antiviral.2013.06.019>



Perspectives on getting to zero

Getting to Zero with HIV Prevention and Treatment Interventions—Is the glass half full or half empty? This was the theme of a post SA AIDS panel discussion with the KwaZulu-Natal Community Forum, organised by the Medical Research Council and In-fo4Africa, to share advances in biomedical and behavioural interventions to turn the tide of HIV infection.

The distinguished panellists included Professor Quarraisha Abdool Karim, CAPRISA Scientific Director; Professor Jerry Coovadia, Director of Maternal, Adolescent and Child Health; and Dr Heidi van Rooyen, Research Director at the Human Sciences Research Council.

Reflecting on the epidemic in South Africa, the speakers gave recognition to the many achievements already made in the HIV/AIDS response. These included the significant reduction in mother-to-child transmission rates, and the roll-out of a comprehensive HIV treatment programme, which have positively impacted quality of life and life expectancy in South Africa. These successes have taken place in spite of the challenges en-

countered concerning inefficiencies in implementing public sector programmes, and despite medical advances usually taking decades to reach South Africa.

Science in the form of prophylactic use of antiretrovirals— whether in tablet or microbicide form— as well as medical male circumcision (MMC), have shown that ‘the cup is half full’. Part of the solution to getting to zero lies in the continued research and development of much needed additional HIV-prevention choices, that can be used by women, in particular. Using the example of how multiple contraceptive choices can be incorporated to suit women’s different life stages, Professor Abdool Karim said, ‘When science shows evidence to support multiple options, people like choice.’

To build on the huge gains from scientific evidence already gathered, researchers need to increase their knowledge of the behavioural challenges that affect acceptability and/or use of effective HIV-prevention methods. ‘Bridging the gap’ with adolescents, particularly young women, posed a significant challenge and their inclusion in biomedical trials was deemed to be a priority. According to Dr van Rooyen lower rates of condom use, slow MMC uptake (possibly attributed to young men to being dissuaded by the bad press associated with traditional circumcision) and the struggle to encourage men to access HIV services were all

Obituary: Pius Langa

It was with deep sadness that CAPRISA learnt of the loss of former Chief Justice Pius Langa at the age of 74 after a long illness. Justice Langa was a member of CAPRISA’s Board of Control.



‘He was a strong supporter of CAPRISA since it was created in 2002 when he was the Chancellor of the University. We shall sorely miss his wise counsel, support and friendship,’ commented CAPRISA Director, Professor Salim Abdool Karim.

Justice Langa’s long and distinguished legal career, which had humble beginnings as a factory worker to finance his law studies, saw him rise to the top judicial post in South Africa, the Constitutional Court.

Described as a true ‘jurist’, Justice Langa received many awards for advancing justice and human rights.

cause for concern. ‘Enthusiasm for some good practices has fallen away,’ she said.

Moving forward, further behavioural studies would be needed to fully comprehend the effect of social and cultural issues on the acceptance of HIV prevention methods.

Intensifying campaigns around intergenerational relationships and condom use was proposed as a way to build on past efforts to promote awareness.

Lastly, a review of counselling and testing programmes and the expansion of its services into more remote areas was considered as the key to motivate more people to have an HIV test.



From left: Professor Jerry Coovadia, Professor Quarraisha Abdool Karim and Dr Heidi van Rooyen



Top 200 list for Vivek

CAPRISA congratulates Dr Vivek Naranbhai, CAPRISA Research Associate, who was named in the top 200 Young South Africans 2013 published by the Mail and Guardian. Now in its eighth year, the list honours 'interesting young people doing amazing things' across diverse disciplines.

Vivek has published several scientific papers on his HIV research and is currently studying for his doctorate in Infectious Disease Immunology on a Rhodes Scholarship at Oxford University.



Fogarty Meet & Greet

A Fogarty meet-and-greet was held during the recent SA AIDS Conference in Durban to encourage networking amongst current and past CAPRISA trainees as well as with faculty members. During her welcome address, CAPRISA Deputy Director, Dr Nesri Padayatchi, highlighted the current recruitment for US traineeships and mentioned the importance of previous trainees providing regular updates for the Careertrac database.



From left: Grace London (recipient of the Discovery Health Clinical Excellence Award presented at the SA AIDS 2013 conference), Priscilla Dlamini, Ashraf Kagee, Bronwynne Coetzee



The celebration of Nelson Mandela's birthday on 18 July, also known as Mandela Day, has grown into an international social movement encouraging nation building through *uBuntu* (humanity to others).

CAPRISA's staff answered the call to perform a *Mandela deed*, by pledging funds, donating produce and preparing meals for the children of the Mafakatini Home Base Care in Vulindlela, Carrington Primary in Umhlobo and Brooklyn Primary School in Chatsworth.



Top left clockwise: Mafakatini Home Base Care enjoying lunch; staff from CAPRISA and Carrington Primary doing food preparation in the kitchen; Brooklyn Primary school children at play time; the production line for meal service.

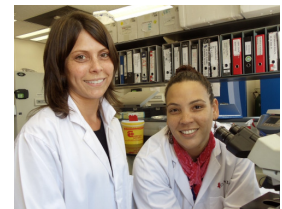
Visits to CAPRISA

CAPRISA hosted study partner CONRAD at its Vulindlela and eThekweni Clinical Research Sites for discussions with the CAPRISA 008 Tenofovir Gel Implementation Study teams.



From left: Ms Tracey Webster (CONRAD clinical research consultant), Ms Neli Nkomonde (CAP 008 project coordinator), Dr Leila Mansoor (CAP 008 Co-principal investigator), Dr Jill Schwartz (CONRAD medical director), Ms Susan Ju (CONRAD project director), Mr Mdu Mntambo (CAPRISA Senior Scientist), Ms Tanuja Gengiah (CAPRISA head of pharmacy).

FHI 360's Senior Clinical Research Manager, Ms Amanda Troxler, spent two days at the CAPRISA offices to monitor progress on the HPV, inflammation and HIV infection risk project.



Amanda (left) is pictured with Dr Lenine Liebenberg (CAPRISA post doctoral fellow).

As part of the *Women in Leadership and Leverage (WILL)* outreach programme by University of KwaZulu-Natal (UKZN) academics, school girls from Tongaat High School visited CAPRISA to learn about its research activities. This year's WILL initiative targeted learners who were keen on pursuing a career in the sciences. The group was particularly thrilled to learn that our Professor Quarraisha Abdool Karim also completed high school at Tongaat High.



Tongaat High School learners during their career orientation day at UKZN's Nelson R Mandela School of Medicine



Scientific papers published in 2013

29* **Abdool Karim SS.** HIV pre-exposure prophylaxis in injecting drug users. *Lancet* 2013 381(9883):2060-2

30 **Baxter C, Yende-Zuma N, Tshabalala P, Abdool Karim Q, Abdool Karim SS.** Safety of coitally administered tenofovir 1% gel, a vaginal microbicide, in chronic hepatitis B virus carriers: Results from the CAPRISA 004 trial. *Antiviral Research* 2013; 99: 405-408 <http://dx.doi.org/10.1016/j.antiviral.2013.06.019>

31 **Abdool Karim Q, Bayer R.** Anti-retrovirals for treatment and prevention - time for new paradigms in our response to the HIV/AIDS epidemic? *Developing World Bioethics* 2013; 13(2): ii-iii. doi:10.1111/dewb.12033

32 **Singh JA.** Why vulnerable young women at risk of HIV should be prioritized for access to preexposure prophylaxis. *AIDS* 2013; 27: 1998–1999.

33 Liu MKP, Hawkins N, Ritchie AJ, Ganusov VV, Whale V, Brackenridge S, Li H, Pavlicek JW, Cai F, **Rose-Abrahams M, Treurnicht F, Hraber P, Riou C, Gray C, Ferrari G, Tanner R, Ping LH, Anderson JA, Swanstrom R, Cohen M, Abdool Karim SS, Haynes B, Borrow P, Perelson AS, Shaw GM, Hahn BH, Williamson C, Korber BT, Gao F, Self S, McMichael A, Goonetilleke N.** Vertical T cell immunodominance and epitope entropy determine HIV-1 escape. *Journal of Clinical Investigation* 2013; 123(1): 380-393.

*continuation from previous newsletter



Scientific Reviews

Abstracts submitted for review		Manuscripts submitted for review		Ancillary studies submitted for review	
Total [#]	Cumulative [^]	Total [#]	Cumulative [^]	Total [#]	Cumulative [^]
0	298	1	166	2	52

for month, ^ since committee initiation

Conference & Workshop Reminders

Conference	Dates	Deadlines		Website
		Abstracts	Registration	
AIDS Vaccine 2013 — Barcelona, Spain	7-10 Oct 2013	11 Aug 2013	22 Sep 2013	www.vaccineenterprise.org/conference/2013/
New HIV Vaccine & Microbicide Advocacy Society: Biomedical HIV Prevention Forum — Abuja, Nigeria	18-20 Nov 2013	TBA	TBA	http://www.nhvmas-ng.org
17th International Conference on HIV & STIs in Africa — Cape Town, South Africa	7-11 Dec 2013	5 Jul 2013	22 Nov 2013	www.icasa2013southafrica.org/
'Inflammation and chronic hepatitis/HIV infections: Who is the driver' Workshop — Milan, Italy	30-31 Jan 2014	10 Dec 2013	(early) 20 Oct 2013	http://www.inflammation2014.com
HIV Research for Prevention 2014: AIDS Vaccine, Microbicide & ARV-based Prevention Science — Cape Town, South Africa	28-31 Oct 2014	TBA	TBA	www.hivr4p.org

CAPRISA is an official research institute of the University of KwaZulu-Natal and Columbia University.

CAPRISA was established in 2002 through a CIPRA grant from the NIH, as a multi-institutional collaboration, incorporated as an independent non-profit AIDS Research Organization

Registration Number: 2002/024027/08

www.caprisa.org