



## **STEFANO VELLA, MD**

### ***Education***

*Degree in Medicine, University of Rome, 1977*

*Specialty in Infectious Diseases, University of Rome, 1982*

*Specialty in Internal Medicine, University of Rome, 1988*

### ***Current position***

*Director, National Center for Global Health*

*Istituto Superiore di Sanità - ISS [The Italian National Institute of Health]*

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### ***Languages***

Fluent in English, French and Spanish

### ***International Appointments***

- President, International AIDS Society [IAS] (2000-2002)
- Organizing Committee – International AIDS Conference, Durban (2000), Barcelona (2002)
- ACTG Research Agenda Committee, NIAID, NIH (2000-2004)
- Program Coordinating Board, UNAIDS (2000-2004)
- Speaker, UN General Assembly Special Session on AIDS (2001)
- Technical Review Panel, Global Fund to fight Tuberculosis, AIDS and Malaria, (2004-2005)
- Board Member, Global Fund to fight Tuberculosis, AIDS and Malaria (2006-2007)
- Scientific Advice Working Party, EMEA, London (2003-2006)
- Co-Chair, IAS Conference on HIV Pathogenesis, Treatment and Prevention (Rome, 2011).
- Board Member (IT), EDCTP - European Commission, La Hague, (2002-2014)
- Chair, European AIDS Treatment Network (NEAT), EC, Brussels (2007-2013)
- Program Committee, 7<sup>th</sup> Framework Program, Health Research, EC (2007- 2013)
- Chair, Clinical Panel for the revision of antiretroviral guidelines – WHO (2013)
- International Review Committee, NIAID, NIH, USA
- Vice-President, Friends of Global Fund, Europe
- Governing Council, International AIDS Society, Geneva

- Vice-President, Scientific Advisory Board, ANRS, Paris, France
- Scientific and Technical Scientific Committee (STAC), UNAIDS, Geneva
- Vice- Chair, EDCTP2 Board (European and Developing Countries Clinical Trial Partnership – EC Joint Initiative), Den Haag, The Netherlands
- International reviewer, UNITAID, Geneva
- Core Group, Panel for the revision of antiretroviral guidelines, WHO (2015)

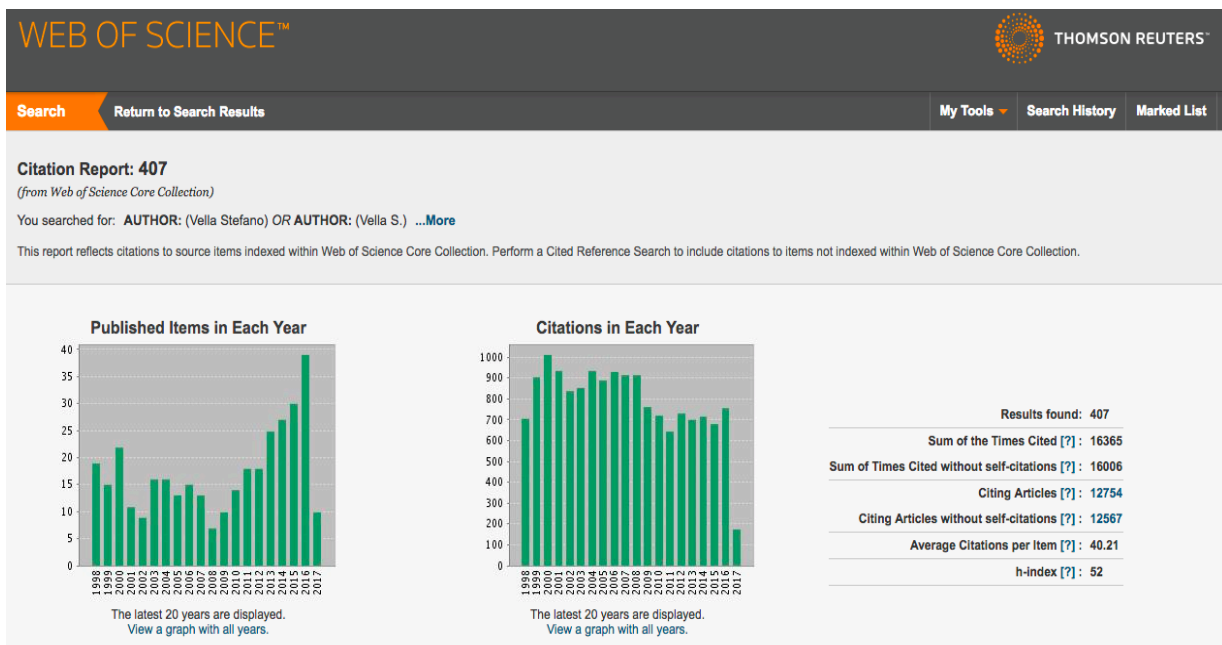
### Invited lectures / Editorial activities

Dr Vella, has been an invited plenary speaker in over 200 International Conferences. He is an article reviewer for numerous journals, including *Science*, *Lancet*, *Journal of Infectious Diseases*, *AIDS*, *JAIDS*.

### Publications

Dr Vella has published more than 400 articles in international journals, including The New England Journal of Medicine, Lancet, JAMA, British Medical Journal, Annals of Internal Medicine, Journal of Infectious Diseases, AIDS, Journal of AIDS.

**H-INDEX: 52 – Citations: > 16.000**



### Biosketch

- Stefano Vella (born in Rome, June 12, 1952) received his degree in Medicine from the University of Rome in 1977. He subsequently achieved specialty degrees in both Infectious Diseases (1982) and Internal Medicine (1987). After a postdoctoral experience at the University of Pennsylvania (1981-1982), he joined the medical staff at the Institute of Internal Medicine, University La Sapienza, Rome,

where he developed an extensive experience in the clinical management of internal medicine and infectious diseases patients.

- In 1991, Dr Vella was appointed Research Director of HIV/AIDS at the Istituto Superiore di Sanità (ISS), the Italian National Institute of Health.

- Specific work has been conducted by Dr Vella and his research group on the clinical development of antiretroviral therapy; the study of HIV resistance to antiretroviral drugs; the mechanisms of immune reconstitution; the care and treatment of co-infections, including TB; the area of health needs assessment; the area of operational and implementation research in resource limited settings.

- At the beginning of the era of combination antiretroviral treatment, he chaired - or participated to - numerous international clinical studies on antiretroviral therapy: including the first studies with protease inhibitors and non-nucleoside reverse transcriptase inhibitors; the strategic studies to assess the best first-line and second line regimens. As a consequence of his work, he was appointed to the Panel who developed the first HIV treatment guidelines (JAMA, 1996). From 2006 till 2013 he chaired the European AIDS Clinical Trials Network (NEAT), funded by the European Commission, involving 40 European partner institutions from 16 countries.

- Since 1996, as Member of the Governing Council of the International AIDS Society [IAS] and subsequently as IAS President (2000-2002), he actively worked towards promoting access to treatment and care in the South of the World and has been instrumental for the organization of the AIDS Conference in Durban, South Africa (2000). He subsequently chaired the 1st IAS Conference on HIV Pathogenesis and Treatment, Buenos Aires, 2001, and the XIV International Conference on AIDS, Barcelona, 2002.

- Scientific advisor of the Italian Cooperation (Ministry of Foreign Affairs) in different African countries, and is involved in the setting of specific operational and implementation programs in Uganda, South Africa, Mozambique, Tanzania, and Ethiopia.

- Member of Technical Review Panel (TRP) of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), where he acquired an extensive experience in the evaluation of country programs to fight poverty-related diseases (he subsequently served as the Italian board member of the GFATM (2006-2007), and is currently a member of the Italian Constituency).

- Member of the General Assembly of EDCTP-2 (European Commission) and vice-chair of the Board.

- Member of the Program Committee of the 7<sup>th</sup> Framework Research Program of the European Commission (DG – Research, Health) and member of the Core Group of the Italian Delegation to Horizon 2020 (Health Research).

- Dr Vella is Vice President of the Scientific Council, ANRS (Agence Nationale de Recherche sur le Sida), Paris, France, and Vice-President of the Friends of Global Fund – Europe.

- Member of the UNAIDS Scientific and Technical Advisory Committee

- Chair of the Panel who developed the 2013 WHO Guidelines on HIV Treatment and Care,

- Member of the Core Group who developed the 2016 WHO HIV/AIDS Guidelines.
- Scientific Advisor of Medicines Patent Pool, (MPP), UNITAID/WHO Geneva
- Member of the of the ART Strategy Committee, ACTG – National Institutes of Health, Bethesda, USA
- From 2003 till 2016 he has been the Director of Department of Pharmacology and Therapeutic Research at ISS (2003-2016), overseeing the research activities of over 270 staff members. In this position he conducted studies on therapeutics of major human disease areas.
- He was a member of the Scientific Advice Working Group (SAWG) of the European Medicines Agency (EMA), London, where he acquired an extensive expertise in the regulatory aspects of the clinical development of medicines, from the preclinical phase to phase III clinical trials.
- In January 2017, Dr Vella was appointed Director of the Italian Center for Global Health at the National Institute of Health, whose mission is to fight health inequalities worldwide through research, education and advocacy.
- In march 2017, Dr Vella has been appointed President of the Italian Medicines Agency (AIFA)

***Expertises:***

Clinical management of infectious diseases and chronic diseases  
     Clinical Pharmacology  
     Randomized Clinical Trials  
     Prospective cohort studies  
     Appropriate use of medicines  
     International Therapy Guidelines  
     Quality of medicines  
     Regulatory aspects of human medicines  
     Drug development  
     Access to medicines  
 Patient education and work with patient communities  
 Coordination and Management of international research projects  
     European Health Research  
     Evaluation of International Research Programs  
 Work with International Organizations and the UN System  
     Health Systems Research  
     Global Health Research  
     Operation and Implementation Research

### ***Selection of publications***

Vella S, Wilson D. Access to medicines: lessons from the HIV response. *Lancet HIV*. 2017 Apr;4(4):e147-e149. doi: 10.1016/S2352-3018(17)30052-8.

Kondili LA, Gaeta GB, Ieluzzi D, Zignego AL, Monti M, Gori A, Soria A, Raimondo G, Filomia R, Di Leo A, Iannone A, Massari M, Corsini R, Gulminetti R, Gatti Comini A, Toniutto P, Dissegna D, Russo FP, Zanetto A, Rumi MG, Brancaccio G, Danieli E, Brunetto MR, Weimer LE, Quaranta MG, Vella S, Puoti M. Real-life data on potential drug-drug interactions in patients with chronic hepatitis C viral infection undergoing antiviral therapy with interferon-free DAAs in the PITER Cohort Study. *PLoS One*. 2017 Feb 28;12(2):e0172159. doi: 10.1371/journal.pone.0172159. eCollection 2017.

Floridia M, Liotta G, Andreotti M, Galluzzo CM, Amici R, Jere H, Sagno JB, Marazzi MC, Buonomo E, Scarcella P, Mancinelli S, Vella S, Giuliano M, Palombi L. Levels of bone markers in a population of infants exposed in utero and during breastfeeding to tenofovir within an Option B+ programme in Malawi. *J Antimicrob Chemother*. 2016 Nov;71(11):3206-3211. Epub 2016 Jul 11.

Floridia M, Liotta G, Andreotti M, Galluzzo CM, Jere H, Sagno J, Mancinelli S, Amici R, Marazzi MC, Vella S, Giuliano M, Palombi L. Serum phosphate and creatinine levels in the first year of life in infants born to HIV-positive mothers receiving tenofovir-based combination regimens during pregnancy and prolonged breastfeeding in an option B+ programme in Malawi [letter]. *JAIDS-Journal of acquired immune deficiency syndromes* 2016;73(5):e90-e91.

Floridia M, Liotta G, Andreotti M, Galluzzo CM, Amici R, Jere H, Sagno J, Marazzi MC, Buonomo E, Scarcella P, Mancinelli S, Vella S, Giuliano M, Palombi L. Levels of bone markers in a population of infants exposed in utero and during breastfeeding to tenofovir within an Option B+ program in Malawi - *Journal of antimicrobial chemotherapy* 2016;71:3206-3211

Vella S, Wilson D. From Durban to Durban: end of AIDS further than hoped. *Lancet HIV*. 2016 Sep;3(9):e403-5. doi: 10.1016/S2352-3018(16)30118-7.

Pirillo MF, Liotta G, Andreotti M, Jere H, Sagno J, Scarcella P, Mancinelli S, Buonomo E, Amici R, Marazzi MC, Vella S, Palombi L, Giuliano M. CMV infection in a cohort of HIV-exposed infants born to mothers receiving antiretroviral therapy during pregnancy and breastfeeding. *Medical microbiology and immunology* 2016;Epub 2016 Sep 15: <http://dx.doi.org/10.1007/s00430-016-0478-6>.

Lazarus JV, Safreed-Harmon K, Barton SE, Costagliola D, Dedes N, Del Amo Valero J, Gatell JM, Baptista-Leite R, Mendão L, Porter K, Vella S, Rockstroh JK. Beyond viral suppression of HIV - the new quality of life frontier. *BMC Med*. 2016 Jun 22;14(1):94. doi: 10.1186/s12916-016-0640-4.

Mancinelli S, Galluzzo CM, Andreotti M, Liotta G, Jere H, Sagno JB, Amici R, Pirillo MF, Scarcella P, Marazzi MC, Vella S, Palombi L, Giuliano M. Virological Response and Drug Resistance 1 and 2 Years Post-Partum in HIV-Infected Women Initiated on Life-Long Antiretroviral Therapy in Malawi. *AIDS Res Hum Retroviruses*. 2016 Aug;32(8):737-42

Casper Rokx, Stefano Vella, Guiseppa Pantaleo, Yves Lévy, Charles A.B. Boucher. Unite forces to validate biomarkers in the quest for lasting HIV remission. *AIDS*. 2016 Jul 17;30(11):1859-60

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- Liotta G, Floridia M, Andreotti M, Jere H, Sagno J, Marazzi MC, Buonomo E, Scarcella P, Mancinelli S, Vella S, Giuliano M, Palombi L. Growth indices in breastfed infants pre and postnatally exposed to tenofovir compared to tenofovir-unexposed infants. *AIDS* 2016; Jan 28; 30(3): 525-527.
- Baroncelli S, Galluzzo CM, Mancinelli S, Andreotti M, Jere H, Amici R, Marazzi MC, Vella S, Palombi L, Giuliano M. Antibodies against pneumococcal capsular polysaccharide in Malawian HIV-positive mothers and their HIV-exposed uninfected children. *Infectious diseases (Lond)*. 2015 Nov 26: 1-5. [Epub ahead of print]
- Palombi L, Pirillo MF, Marchei E, Jere H, Sagno JB, Luhanga R, Floridia M, Andreotti M, Galluzzo CM, Pichini S, Mwenda R, Mancinelli S, Marazzi MC, Vella S, Liotta G, Giuliano M. Concentrations of tenofovir, lamivudine and efavirenz in mothers and children enrolled under the Option B-Plus approach in Malawi. *J Antimicrob Chemother*. 2016 Apr; 71(4): 1027-30. doi: 10.1093/jac/dkv435. Epub 2015 Dec 17.
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- Giuliano M, Liotta G, Andreotti M, Mancinelli S, Buonomo E, Scarcella P, Amici R, Jere H, Sagno JB, Di Gregorio M, Marazzi MC, Vella S, Palombi L. Retention, transfer out and loss to follow-up two years after delivery in a cohort of HIV+ pregnant women in Malawi. *Int J STD AIDS*. 2016 May; 27(6): 462-8. doi: 10.1177/0956462415585450. Epub 2015 May 6.
- Palombi L, Galluzzo CM, Andreotti M, Liotta G, Jere H, Sagno J, Luhanga R, Mancinelli S, Amici R, Marazzi MC, Vella S, Giuliano M. Drug resistance mutations 18 months after discontinuation of nevirapine-based ART for prevention of mother-to-child transmission of HIV in Malawi. *J Antimicrob Chemother* 2015; 70: 2881-2884
- Vella S. Addressing barriers to the end of AIDS by 2030. *Lancet* 2015; 2( 9): e360-e361.
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François Raffi, Abdel G Babiker, Laura Richert, Jean-Michel Molina, Elizabeth C George, Andrea Antinori, José Arribas, Jesper Grarup, Fleur Hudson, Christine Schwimmer, Juliette Saillard, Cédric Wallet, Per O. Jansson, Clotilde Allavena, Remko van Leeuwen, Jean-François Delfraissy, Stefano Vella, Geneviève Chêne, Anton Pozniak, and the NEAT 001/ANRS 143 Study Group. Ritonavir-boosted darunavir combined with raltegravir or tenofovir/emtricitabine in antiretroviral-naïve adults infected with HIV-1: 96 week results from the NEAT001/ANRS143 randomised non-inferiority trial. *Lancet.* 2014 Nov 29;384(9958):1942-51

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Øyvind M, Aotani E, Anderiesz C, Bertoye P, Cazap E, Chan A, Ghersi D, Gouya G, Isaac M, Kvalheim G, Makanga M, Nam B, Ren J, Siegfried N, Steinhausen K, Stuart GCE, Vallikad E, Vaz F, Vella S, Wolzt M, Timble EL. Report from Subgroup Education, Training, Infrastructure and Patient Involvement under OECD GSF Working Group to facilitate international cooperation in non-commercial clinical trials *Japanese pharmacology and therapeutics* 2012; 40(2 Suppl): 137-182.

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