

## **Role Play— Contested Evidence and the challenges of mixed method synthesis**

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As with any role play, the best way to get the most out of the day is to immerse your-self in the particular role you have been allocated.

### **Introduction:**

This role play seeks to identify the challenges of synthesising mixed evidence for evaluation. Realist synthesis is not a technique but an analytical process. It does not seek to identify what works, rather a realist approach asks the questions “*what* is it about an intervention that works, for *whom*, in what *circumstances*, in what *respects* and *why*?” (Pawson, 2006:94—emphasis in the original). These kinds of explanation are achieved through embracing a catholic and non-hierarchical approach to accepting what constitutes evidence—a contextual description of an intervention may be of equivalent appropriateness in the review to a double blind randomised control trial, for instance. Analysis of the evidence accumulated in the review is through an iterative and reflexive approach to generate and refine theory towards a goal of explanation building.

The example of the distribution of anti-retroviral drugs in South Africa is a particularly interesting case to examine using a realist approach: it is a highly political topic that has attracted a range of competing evidence to support different policy positions. Post-apartheid South Africa has had to contend with high rates of HIV infection, a highly mobile population often across its international borders, limited resources to address the health of the population, and a legacy of apartheid public health which focussed its attention on the white population at the expense of the black majority. Post-apartheid South Africa has also taken on the mantle of leader among low-income countries, seeking to address the perceived inequities associated with the global trade in pharmaceuticals, poverty, and inequalities in health. It is within this context that the leadership of the South African Government has sought different kinds of evidence to inform its policies on the distribution of anti-retroviral drugs to extend the lives of those living with HIV/AIDS.

Today’s role play considers the range of potential evidence that is available to policy makers in evaluating their policy and programme options and that might inform a realist synthesis. In the morning session you are asked to work in your groups to consider the position of your group and the evidence available to you with reference to anti-retroviral drug policy in South Africa. Your task is to arrive at a theoretical position, derived from the evidence, about how anti-retroviral drugs might be most effectively distributed to the South African population to ameliorate the symptoms (and in the case of vertical transmission between mother and child, prevent transmission) of HIV/AIDS. In the afternoon session you are asked to negotiate your working theory for the distribution of these drugs with the other groups who may have different kinds of evidence and different theoretical positions based on their synthesis of their evidence.

Pawson R (2006) Evidence-based policy: A realist perspective. Sage. London.

## Learning objectives:

- To consider the value of the different evidence available to you to understand the context in which public distribution of anti-retroviral drugs might be distributed in South Africa.
- To identify mechanisms for the effective distribution of anti-retroviral drugs through synthesis of the evidence available to you.
- To consider the challenges of an iterative and reflexive realist synthesis.

In the morning session you will:

- Juxtapose, adjudicate, reconcile, and situate evidence towards a theory about how interventions to distribute anti-retroviral drugs to address HIV/AIDS in South Africa might be most effectively carried out.

In the afternoon session you will:

- Consider how competing theoretical positions for interventions and the evidence they are built might be accepted or rejected to arrive at a policy to address anti-retroviral distribution in South Africa

## Participants:

President Thabo Mbeki and vice-president Justin Malewezi and aide (the speakers)	Wants to be seen as moral and political leader of this issue; angry at northern/donor intervention. Feeling under pressure from strong pro-ARV coalition. Worried about serious economic challenges his health sector faces. Addressing governance in post-Apartheid South Africa
AIDS Task Committee	Strong supporters of Mbeki, but increasingly concerned by growing national and international pressure to back down over ARVs
Public health doctors and scientists	Argue for the efficacy of treatment and also observe that the UK and US multinational drug companies exaggerate the cost of research and focus their expenditure on profitable medicines to address the conditions of people in rich countries
Dissident scientists and activists	Intent on challenging 'given' international scientific knowledge in the name of freedom of expression and scientific enquiry. Convinced that there is no 'proved' causal link between HIV and AIDs, but given international outrage at that position, their main line of argument now is that there is no proven benefit of ARV on HIV condition/AIDs development, and there is evidence (in the West) to suggest that drug cocktails like Nevirapine could be positively detrimental to health.
Treatment Action Campaign (TAC), Health Systems Trust (HST) and Medecines Sans frontiers (MSF) representatives.	Strong coalition of advocacy, lobbying and research organisations. HST currently doing pilot test of Nevirapine at request of Government; MSF also involved in pilot trials with imported generic drugs (against Government wishes). TAC is main lobbyist and has brought and won a number of cases against government – others still pending.

UK and US Multinational Pharmaceutical company Representatives	Driven largely by commercial interests: South Africa represents a potentially large expansion of markets with a foothold to the rest of the continent. Also desire to be seen as 'humanitarian' in their offers to donate drugs and offer discounted products. Keen to re-establish their reputations in response to their failed court case against the government. Concerned about manufacture and promotion of generic drugs and possibilities of relaxing international patent laws.
Cipla Representatives	Parallel manufacturer and importer of combination ARVs based in India. In talks with a variety of South African private sector companies. Support from TAC/MSF.
WTO and DFID reps	Seek to uphold British and international trade interests through established international institutions and agreements including: TRIPS, GATS and the Global Fund. Also keen to win the South African government on to their 'side'.
Women Living with AIDS	Women are disproportionately vulnerable to HIV/AIDS; many women in South Africa continue to be discriminated against. A group of women activists is beginning to make themselves heard and have taken inspiration and support from the Canadian-based 'Women's Health Interaction'
Gender AIDS Forum	This is a new group established to promote the view that the focus in current public and government discourse on AIDS treatment actually overshadows one of the key root causes of HIV/AIDS which is gender inequality. The group claims that TAC ignores women's sexual and reproductive rights in its campaign and argue that while treatment is important, the Government should remember that prevention is better than treatment and that national AIDS policies should take a broader approach to the problem. They call for government commitment to tackling gender inequality, particularly in sexual and reproductive health matters.

### **The outcome of the day's activities:**

The speakers will be taking on the parts of President Thabo Mbeki and vice-president Justin Malewezi and their aides. Each group should seek an audience with the President during the morning to explain the position they have taken in the synthesis—their theory about how an intervention to distribute anti-retroviral drugs in South Africa's public health system can most effectively be implemented. Each group should consider what evidence is used and what rejected.

In the afternoon, each group should note how their theoretical position is moulded and changed through interactions with the other groups and should be able to report this to the President and in the final summing up session.

We can not expect to do a realist synthesis review in the short time we have available to us today. However, the intention is to highlight the iterative and reflexive approach to explanation building that is the principle of realist synthesis.

## An outline timetable:

10.00-10.10	Introduction Susie Mayhew and Nick Emmel—the aims of the day and an introduction to the role play
10.10-10.40	Video-The Price of Life—an of the challenges of HIV AIDS in South Africa that introduces evidence important in your synthesis
10.40-12.10	Group working on role play—synthesising the evidence for a particular position in the HIV/AIDS role play
12.10-12.30	Ray Pawson—synthesis in mixed method evaluation
12.30-13.30	Lunch
13.30-13.50	Mary Godfrey—The impact of different perspectives in mixed-method evaluation
13.50-14.10	Jane Fielding—Insider and outsider perspectives in mixed method evaluation
14.10-15.30	Interaction between groups—synthesising different positions in mixed method evaluation in the HIV/AIDS role play
15.30-16.00	Report back from the role play and concluding observations on the challenges and opportunities of realist synthesis (All speakers)

## A guide to AntiRetroVirals (ARVs):

**Nucleoside reverse transcriptase inhibitors:** slow down production of reverse transcriptase enzyme that HIV needs to turn RNA into DNA

Name	UK price	Africa price	Made by
Abacavir	2901.75	631.45	GSK
Stavudine (d4T)	922.80	33.37	Bristol-Myers Sqib
Zidovudine (AZT or ZDV)	3485.75	281.05	GSK and Cipla
Didanosine (ddl)	1338.33	189.09	Bristol-Myers Sqib
Lamivudine	1989.25	146.65	GSK

**Protease inhibitors:** works on the enzyme which breaks down proteins, HIV uses protease to reproduce itself when the viral DNA reaches the nucleus of a host cell

Name	UK price	Africa price	Made by
Indinavir	2469.44	366.03	Crixivan
Saquinavir	3808.41	1079.00	Hoffman La Roche
Rionavir	4528.68	304.77	Abbott Laboratories
Nelfinavir	3535.07	496.08	Roche
Lopinavir + Rionavir	3987.72	304.77	Abbott Laboratories

**Non-nucleoside reverse transcriptase inhibitors:** block production of transcriptase and bind the cell's reverse transcriptase

Name	UK price	Africa price	Made by
Efavirenz	2689.08	216.71	Bristol Myers Squibb
Nevirapine	2016.00	271.35	Boehinger

**Combination drugs:** combine some of all the types above, and are sold at low prices by generic companies. These combination drugs make treatment far simpler in low-income countries. Patents prevent the European and US companies from combining their own drugs with those of their competitors.

Name	UK price	Africa price	Made by
Dovir N	n/a	258.96	Cipla
Triomune	n/a	188.34	Cipla
Combivir	4110.96	384.42	GSK
Trizivir	6960.76	974.76	GSK

All prices in £s sterling are for per-patient per-year, and may not include local taxes and account for currency variation (source: Guardian 18.02.03:9)

## Key Background Readings (all groups)

### Background

- Mbeki's speech to opening session of 13<sup>th</sup> International AIDS Conference, Durban 9<sup>th</sup> July 2000
- Fassin D. and Schneider H. (2003) 'The politics of AIDS in South Africa: beyond the controversies' *BMJ* vol. 326:495-7

### South African health system and AIDS policies

- 'South Africa: an overview – health': information from South African Government website.
- Millennium development Goals: South Africa Country Profile: document from World Bank website: [www.devdata.worldbank.org/idg/IDGProfile.asp/](http://www.devdata.worldbank.org/idg/IDGProfile.asp/)
- Update on the National HIV and AIDS Programme, 23<sup>rd</sup> November 2005: document from South African Government website: [www.gov.za/issues/hiv/](http://www.gov.za/issues/hiv/)
- UNAIDS South Africa Country pages 2004

### International aid and controversy

- Attaran A. and Sachs J. (2001) 'Defining and refining international donor support for combating the AIDS pandemic' *The Lancet* vol.357, Jan.6<sup>th</sup> 2001:57-61
- Ainsworth M. and Teokul W. (2000) 'Breaking the silence: setting realistic priorities for AIDS control in less-developed countries' *The Lancet* vol.356, July 1, 2000:55-60

In addition, each stakeholder/group of stakeholders will receive an individual reading pack to help them prepare for the workshop.

## Readings for characters:

### President Thabo Mbeki and Vice-President Justin Malewezi

#### AIDS Task Committee

#### Public health doctor and Scientist

- Partnership against AIDS declaration 9<sup>th</sup> October 1998;
- Interim Report of the Presidential AIDS Advisory Panel report, March 2001 (recommendations and conclusion) + media release of 4<sup>th</sup> April 2001;
- Statement on Court Decision on Nevirapine 14/12/2001 + Minister for Health speech on response to judgement on Nevirapine 19/12/2001 + Circular on administration of Nevirapine (media release + MoH guidelines) 16<sup>th</sup> April 2002;
- Cabinet statement on HIV/AIDS of 17<sup>th</sup> April 2002 and summary of Government's position (same date) (implementation of HIV policy);
- S. Africa AIDS drug campaign grows, targets minister' Gershwin Wanneburg, *Reuters* 25<sup>th</sup> March 2003.
- 2 articles from *Le Monde Diplomatique*: Bulard (2000) 'Apartheid of Pharmacology' January 2000. Demenet (2002) 'The High Cost of Living', February 2002.
- Mbeki speech in CityPress, Feb 2006

*For further information see the South African Government website for policy documents, cabinet statements and press releases etc. [www.gov.za/](http://www.gov.za/)*

#### Dissident Scientist and activist

- 'A Critical analysis of the pharmacology of AZT and its use in AIDS' Papadopoulos E. et al. *Current Medical Research and Opinion* Vol.15 Supplement, 1999 (excerpts);
- Perth Group Commentary on the Durban Declaration, 12<sup>th</sup> August 2000 (letter and commentary rejected by Editor of *Nature* on 12<sup>th</sup> September 2000);
- Open letter to Glaxo-Smith-Kline by Anthony Brink, March 2001 (against production and sale of AZT);
- 'South Africa drugs authority reviewing Nevirapine' *Business Day* (South Africa), 22 March 2002 +2 Reuters and 1 AP news update on same topic, of 22<sup>nd</sup> March 2002.
- Epstein (1996) 'Credible knowledge, hierarchies or expertise and the politics of participation in biomedicine', in *Impure Science. AIDS, Activism and the Politics of Knowledge*, Berkeley, California University Press: 330 - 53

*For further information see the **virusmyth** website: [www:virusmyth.net/aids/](http://www.virusmyth.net/aids/)*

#### Treatment Action Campaign (TAC, Health Systems Trust (HST) and Medecines sans Frontiers (MSF).

- Weissman R (1999) 'AIDS and Developing countries: democratizing access to essential medicines' Vol.4(23):August 1999;
- 'Interim findings on the national Prevention of Mother-to-Child Transmission (PMTCT) Pilot sites: lessons and recommendations, HST, Feb 2002;

- ‘Defiance campaign’ TAC March 2000: 3 documents: ‘Defiance campaign against Patent Abuse and AIDS Profiteering by Drug Companies’ and Qs and As about TAC and MSF importing generic medicines from Brazil’; ‘Dying for Treatment’ TAC Briefing on the civil disobedience campaign, March 2003.
- ‘Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries’ (3<sup>rd</sup> edition) MSF Campaign for Access to Essential Medicines, 1<sup>st</sup> December 2002;
- JCSMF Minutes: Progress on Operational Plan for HIV/AIDS, 18<sup>th</sup> Feb 2005.
- TAC newsletter Feb 2006.

For further information on court action, official campaign and legal (court action) documents see: [www.cptech.org/ip/health/sa/](http://www.cptech.org/ip/health/sa/), [www.tac.org.za/](http://www.tac.org.za/) and [www.hst.org.za/pubs/pmtct/](http://www.hst.org.za/pubs/pmtct/)

### **UK and US Multinational Pharmaceutical company Representatives**

- 2 Press releases from Pharmaceutical Research and Manufacturers Association on development of new medicines for HIV/AIDS
- UK Government Initiatives: promoting access in the developing world – a profitable business. 1-page brief from GPC International (UK marketing company for international Pharmaceutical companies).
- ‘Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries’ (3<sup>rd</sup> edition) MSF Campaign for Access to Essential Medicines, 1<sup>st</sup> December 2002;
- Bond P. (date?) ‘Globalisation, Pharmaceutical Pricing, and South Africa Health Policy: Managing Confrontation with U.S. Firms and Politicians’ *International Journal of Health Services* vol. 29(4):
- 2 articles from *Le Monde Diplomatique*: Bulard (2000) ‘Apartheid of Pharmacology’ January 2000. Demenet (2002) ‘The High Cost of Living’, February 2002.

For further information see: Office of the U.S. Trade Representative – [www.ustr.gov/](http://www.ustr.gov/), Pharmaceutical Research and Manufacturers of America – [www.phrma.org/](http://www.phrma.org/) and Consumer Project on Technology [www.cptech.org/](http://www.cptech.org/)

### **Cipla Representatives**

- CIPLA in the news: series of news articles.
- ‘Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries’ (3<sup>rd</sup> edition) MSF Campaign for Access to Essential Medicines, 1<sup>st</sup> December 2002;
- Bond P. (date?) ‘Globalisation, Pharmaceutical Pricing, and South Africa Health Policy: Managing Confrontation with U.S. Firms and Politicians’ *International Journal of Health Services* vol. 29(4):
- Shah A. (2002) ‘Pharmaceutical Companies and AIDS’ Web document on Corporations and health: [www.globalissues.org/TradeRelated/Corporations/AIDS.asp](http://www.globalissues.org/TradeRelated/Corporations/AIDS.asp)
- 2 articles from *Le Monde Diplomatique*: Bulard (2000) ‘Apartheid of Pharmacology’ January 2000. Demenet (2002) ‘The High Cost of Living’, February 2002.

For further information see the Cipla website: [www.cipla.com/](http://www.cipla.com/)

### **WTO and DFID Representatives**

- WHO Briefing on TRIPs, August 2000.
- Briefings on Global Fund: US State department, Global Fund website and CPTECH press release on NGO demands for Global Fund.
- Sexton S. (2003) 'Trading Health Care Away? GATS, Public Services and Privatisation': Bulletin 15, South Centre, 2003 – summary of Briefing 23, The Corner House, July 2001. Document from South Centre website: [www.southcentre.org/info/southbulletin/bulletin15/southbulletin15-03.htm](http://www.southcentre.org/info/southbulletin/bulletin15/southbulletin15-03.htm)
- UK Government Initiatives: promoting access in the developing world – a profitable business. 1-page brief from GPC International (UK marketing company for international Pharmaceutical companies).
- Bond P. (date?) 'Globalisation, Pharmaceutical Pricing, and South Africa Health Policy: Managing Confrontation with U.S. Firms and Politicians' *International Journal of Health Services* vol. 29(4):
- 2 articles from *Le Monde Diplomatique*: Bulard (2000) 'Apartheid of Pharmacology' January 2000. Demenet (2002) 'The High Cost of Living', February 2002.

### **Women Living with AIDS**

- Women's Health Interaction (1999) *Uncommon Questions: A feminist exploration of AIDS*, WIH, Ottawa, 1999.
- Epstein (1996) 'Credible knowledge hierarchies or expertise and the politics of participation in biomedicine', in *Impure Science. AIDS, Activism and the Politics of Knowledge*, Berkeley, California University Press: 330 - 53

### **Gender AIDS Forum**

- 2 News articles: 'South Africa: Gender equality needed in national HIV/AIDS Policy' (PLUSNEWS 8<sup>th</sup> Nov 2004); 'SA's push for gender equity' (South Africa info) June 2002.
- 2 Dossiers on Gender and HIV/AIDS from Eldis/BRIDGE website
- 1 conference abstract 'Advocating for microbicides using a sexual health framework', March 2004 and Plenary presentation by Sisonke Msimang (UNIFEM, South Africa) at the International Forum of Association of Women's Rights in Development, October 2002.
- Background information sheet on Gender in South Africa