

**A COMPARATIVE ANALYSIS OF UK AND AUSTRALIAN METHODS
FOR EVALUATING HIV INNOVATIVE HEALTH TECHNOLOGIES**

EVALUATION FELLOWSHIP REPORT

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Transitions in HIV Management: innovative health technologies'

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INTRODUCTION

This report is based on a visit to the National Centre in HIV Social Research (NCHSR), University New South Wales (UNSW) in March/April 2003. The purpose of the visit was to compare Australian and UK methods of evaluating HIV innovative health technologies (IHTs). At this time, HIV IHTs are primarily understood as HIV anti-retroviral combination therapies and associated diagnostic tests. In the UK, a two-year qualitative study is being undertaken to investigate the ways in which these medical technologies are effecting and are effected by the cultures of those living with and/or working with HIV. The study is titled 'Transitions in HIV management: innovative health technologies.' It is funded by the Innovative Health Technologies Programme, UK Economic Social Research Council. It provides the main basis for the comparison with a series of similar qualitative studies undertaken by the NCHSR.

BACKGROUND TO NATIONAL CENTRE IN HIV SOCIAL RESEARCH

The National Centre in HIV Social Research (NCHSR) is internationally recognised for its contribution to the prevention of HIV since early in the epidemic. Its main focus has been to provide social research that assists policy makers and educators to achieve a high standard of prevention within Australia. In undertaking this work, the NCHSR has proved itself a leading contributor in innovative HIV research design (for example, the devising of an optimism scale now adapted for use by others, recognition of 'negotiated safety' and 'strategic positioning'). The NCHSR is also active in supporting HIV research in Asia and Africa.

Research undertaken by the NCHSR on the effect of medical technologies commenced with the recognition that the HIV antibody test was being used by gay men to establish HIV seroconcordance with a regular partner in order to have unprotected anal intercourse (Kippax et al. 1993). The advent of HIV anti-retroviral combination therapy has led to a number of research projects. These include studies on whether the therapies may be responsible for changes to gay sexual culture (Slavin et al. 1998, Rosengarten et al, 2000), the way in which current therapies and associated tests are affecting the lived experience of being HIV positive (Race and Wakeford 2000, Persson 2002), doctor/patient relations (Race et al, 2002), and on social construction of HIV IHTs in the media and educational material (Race 2001a, b). In addition to research undertaken on the impact of anti-retroviral therapy, the NCHSR is now undertaking a large quantitative study called 'Health in Men' (HIM) in preparation for the possible social effects of an HIV vaccine trial.

The NCHSR receives its core funding from the Australian Commonwealth Department of Health and additional project grants from state government bodies, national research councils and international funding bodies. Research undertaken on the social implications of medical technologies is funded through a core position dedicated to HIV positive research with additional research money from other bodies as required. The NCHSR is located within the Faculty of Arts at the University of New South Wales in Sydney. This location provides an important disciplinary base for facilitating and undertaking of collaborative research with a range of partners.

At present the NCHSR is involved in partnerships at the national and international level. These include government and non-government organisations, particularly those representative of HIV affected communities. The partnership approach is seen to ensure relevant research as well as an effective interface with members engaged in programme development, delivery and representing HIV affected communities. Partnerships occur in a number of ways: through membership on the NCHSR's Scientific Advisory Committee, through formal and informal consultations, and through research advisory groups.

RESEARCH ACTIVITIES

Proposed Activities

A series of activities were proposed prior to the visit to the NCHSR with the aim of identifying areas of similarity and difference in research on HIV IHTs as well as identifying possible future areas for collaboration. They were as follows:

- Meet Director Professor Susan Kippax, Deputy Director Dr Paul Van de Ven and research staff working on HIV IHT projects.
- Meet with voluntary and public sector representatives currently involved in treatment information and in policy development on HIV IHTs.
- Present seminar paper on media analysis of the construction of the HIV IHT consumer/patient.
- Access data on the experience of HIV IHTs by people living with HIV and medical practitioners to develop an international database (for example, data from 'Positive Health study,' 'HIV Health in Context,' and 'The Side Effects Project: Living With HIV Treatment Side Effects and Body Shape Change').
- Review NCHSR evaluations of HIV IHTs including methods, archival material, reports and publications.
- Explore potential for future collaboration with NCHSR.
- Complete first draft of journal article on HIV IHT medical culture

Activities Undertaken

The activities undertaken were consistent with those proposed, with the exception of the completion of a first draft of an article on HIV innovative health technology (IHT) medical culture. Work on this article is still underway. Particularly productive were the numerous formal and informal discussions held with NCHSR staff, other academic staff within the Faculty, academic staff from University of Western Sydney, University of Sydney and also representatives from government and non-government organisations. The discussions provided valuable exchange of ideas on current issues posed by HIV innovative health technologies (IHTs) and methodological approaches for investigating these. The discussions also provided an introduction to past and current research on IHTs, prior to review of articles, reports and some interview data. The seminar enabled a broader style of exchange to take place in which participants offered various perspectives on HIV IHTs.

Below is a list of formal meetings conducted with key people at the NCHSR and in the government and non-voluntary sector. These meetings covered issues raised by HIV IHTs. The list of meetings is followed by other activities. These include presentation of seminar paper and review of relevant qualitative research by the NCHSR (see Appendix).

- **Meetings with NCHSR Staff:**

Professor Susan Kippax, Director.

Dr Paul Van de Ven, Deputy Director.

Mr Kane Race, (previously Research Fellow) PhD student.

Mr Dean Murphy, Communications & Education Liaison Officer.

Dr Asha Persson, Research Officer.

Mr Gary Smith, Research Fellow.

- **Meetings with voluntary and public sector representatives on the role of HIV IHTs:**

Mr Alan Brotherton, Head of Client Services, AIDS Council of NSW

Mr Brent Mackie, AIDS & Infectious Disease Branch, NSW Health.

- **Review NCHSR evaluations of HIV IHTs:**

Discussions with Kane Race and Asha Persson on previous and current research covered ways of identifying and prioritising research topics, choice of methods, and recent findings. On the basis of these discussions a series of reports and papers were reviewed (See Appendix for a list of reports and papers reviewed).

- **Presentation of seminar paper:'**

'Consumer Activism in HIV pharmacology' presented within NCHSR Colloquium Series 20 March. This seminar was advertised through the NCHSR Colloquium Series Email List that includes members of the UNSW Faculty of Arts, staff at the University of Sydney, Australian National University and government and non-government HIV organisations. It was attended by NCHSR staff including the Director, representatives from the National Association of People Living with HIV/AIDS (NAPWA) and from People Living with HIV/AIDS (PLWA), NSW, as well as academic staff from Media Studies, UNSW, Philosophy, UNSW, Research Institute for Humanities and Social Sciences, University of Sydney, and Critical Psychology, University of Western Sydney.

- **Exploration for future collaboration with NCHSR:**

Discussions on this possibility were undertaken with the Professor Kippax, Kane Race, Dean Murphy and Asha Persson. These discussions identified key areas of overlap and potential future research interest. Their outcome is included in Research Findings and taken up in Conclusion and Recommendations.

RESEARCH FINDINGS

Throughout the visit to the NCHSR it was apparent that there is a lively research culture engaged with very similar questions to those under consideration in the UK. It was also apparent that issues identified within the Innovative Health Technology Programme are highly applicable to the Australian context particularly in relation to changes in concepts of risk, ways of dealing with uncertainty, pharmaceutical innovation and promotion, doctor/patient relations as well as the experiential nature of living with HIV and being on combination therapy. However, the opportunity to reflect on research practice both in Australia and the UK also raised new issues and identified a series of areas for further research.

Methodological approaches to researching HIV IHTs were found to be very similar. The main method in both contexts has been in-depth interviews. Other methods in both contexts include media analysis and ethnographic observation methods in the clinic. However, the Australian research has been more focused on pre-identified issues such as dosing adherence, treatment side effects (particularly lipodystrophy and lipoatrophy), and doctor/patient relations (Race & Wakeford 2000, Persson, 2002, Race et al. 2002). The specialised and long term research focus of the NCHSR has also permitted cohort studies whereby participants are re-interviewed every six months as a means of better identifying the changing experiential nature of the epidemic for the person living with HIV (see Appendix: 'HIV Health in Context').

In the UK, the 'Transitions in HIV Management' study has tended towards a broader approach covering many of the issues raised by HIV IHTs in the one study. Epidemiological differences in the nature of the epidemic in the UK, compared to Australia, have also meant that the research needs to be inclusive of not only gay affected communities but also African affected communities. A further difference in the two contexts is the access provided to medical practitioners and nursing staff within the UK compared to Australia. In Australia, HIV is managed through specialist GPs in private practice in contrast to the public provision of UK health services through NHS outpatient clinics. Although the costs to the Australian patient (who has access to medicare cover) are covered by the government, medical practitioners are usually unwilling to give time to researchers as it directly impinges on their individual income. Despite this constriction on research access, it should be noted that the NCHSR has received support from some medical practitioners enabling a study of clinical practice (Race et al. 2002).

Historically, the NCHSR research on medical technologies emerged from findings of studies aimed at assisting HIV prevention. As noted in the background section of this report, the study by Kippax et al (1993) found that gay men utilised the HIV antibody test to establish seroconcordance with a partner in order to have safe unprotected anal intercourse. The recognition that medical technologies may inform social (particularly sexual) practices has been important in the development of further studies about the effects of current HIV IHTs on gay sexual culture (Slavin et al. 1998, Rosengarten et al. 2000). However, research more intensely focused on the way in which HIV IHTs are affecting the lives of people with HIV has also come from a reflexive research practice responsive to the involvement of affected communities and to the shortcomings evident in prevailing medical approaches. Initial work on the implications of HIV IHTs for affected communities began after the introduction of anti-retroviral therapies and at a time when the accepted view was 'hit early, hit hard' with the drugs. The aim of the research was to facilitate the public health policy of treatment compliance. However, shifts in medical assessments of HIV IHTs and the findings of early research made evident the need for a more critical appraisal of the effects of IHTs (Race, 2003 per comm.).

The development of a research profile which involves a critical examination of the way in which users understand and experience medical interventions has lead to more focused studies of specific aspects of HIV IHTs, for example: 'The Side Effects Project: Living With HIV Treatment Side Effects and Body Shape Change' and 'Adherence and Communication: Reports from a study of HIV general practice.' This research has drawn on close links with affected communities in terms of its recruitment of subjects and familiarity with nominated issues of concern. It has translated the nominated issues of concern into a more theorised account of the epidemic, informed by Social Psychology, Science and Technology Studies (STS), theories of risk, and work on the sociology of the body not unlike that found within the IHT programme (ESRC 2001).

Overall the methods used by the NCHSR are comparable with those utilised in the 'Transitions in HIV Management: HIV innovative health technologies' study. Both Australian and UK research incorporates in-depth interviews, ethnographic observation and media analysis. Where differences occur they can be traced to structural differences within the field and amongst HIV affected communities. The voluntary sector in Australia is highly cohesive. Each State has its own AIDS Council, which receives State government funding and possibly some funding from the Federal government. At the national level there is a peak co-ordinating agency, Australian Federation of AIDS Organisations (AFAO). It receives funding from the Federal government. There is also a national organisation representing people with HIV, NAPWHA which receives funding from the Federal government and some outside funding from pharmaceutical manufacturers. All of these organisations meet regularly. The voluntary situation is

markedly different to the UK. In the UK there are numerous organisations, some of whom overlap in activities and many who compete for Department of Health funds. To some extent this situation arises from the larger UK population and the different political climates in which the Australian and UK sectors developed.

Below is a brief breakdown of the more apparent structural differences that may be important to consider for future collaboration.

<i>The Australian (Capital City) Research Context</i>	<i>The UK (London & major cities) Research Context</i>
Predominantly gay HIV affected communities	African as well as gay affected communities
HIV medical services delivered by private sector GPs (costs covered by Medicare)	HIV medical services delivered through NHS Out Patient Clinics.
Highly organised voluntary sector.	Competitive disparate voluntary sector
Peak national and state based PLWHA organisations	No officially representative PLWHA organisations

The similarities and differences identified in this section are framed within a paradigm of existing of HIV IHTs. Despite the limitations of this paradigm identified by medical science as well as by social research in the form of drug side effects, to date there is little social research on the possibilities of other approaches.

The NCHSR has recognised the challenge likely to be posed by the introduction of an HIV vaccine (whether it is partially or fully effective). It has also recognised the worrisome nature of a recent proposal to use therapeutic means for prevention purposes, namely, the administering of anti-retroviral drugs for viral suppression as a pre-exposure prophylaxis to sex workers in countries such as Cambodia (Kippax, per. comm.). Both issues highlight the tension that exists between the medical domain and the social (Kippax and Race, In press). They also evidence the danger in an unquestioned acceptance of medical interventions as outside the social rather than shaped by and shaping of it.

CONCLUSION AND RECOMMENDATIONS FOR FUTURE COLLABORATION

The HIV field is currently faced with a series of challenges arising in the context of increasing technological and medical innovation. The overlapping theoretical and empirical interests as well as similarities in negotiating an important relationship with HIV affected communities provides a strong basis for UK/Australian collaboration to address these challenges. It is on the basis of discussions and review of evaluative approaches to HIV innovative health technologies in the UK and Australia that three areas of further research proposed. These areas have support within Australia from the NCHSR and here, in the UK, from the BIOS Centre for the study of bioscience, biomedicine, biotechnology and society, LSE and from the National AIDS Trust.

Topic A: 'Social effects of a vaccine for HIV'

The NCHSR is already undertaking research on the social effects of a vaccine for HIV in anticipation of the commencement of vaccine trials in Sydney. The research has been developed in response to the potential for an HIV vaccine (whether it be fully or only partially effective) to bring about a watershed in HIV medical and social interventions. On the basis of previous research on the effect of existing HIV anti-retroviral therapies and associated tests, this watershed may involve radical alteration of the delivery of HIV medical services and radical re-thinking of the meaning of risk amongst affected communities as well as the broader population. At this stage, the research consists of the Health In Men (HIM) quantitative cohort study to establish base line data. In contrast to Australia, the UK has a much larger population of people likely to be affected by the introduction of an HIV vaccine but, to date, has little research underway on the preparedness of government and voluntary organisations to respond appropriately to community education needs. Taking a lead from the Australian work, it may be possible to develop qualitative research on community perceptions of HIV vaccination including conceptions of risk, infectivity, and immunity. This qualitative research could be developed in conjunction with Australian quantitative research questions and could, in turn, enhance the Australian findings for an international audience.

Topic B: 'The role of user involvement in the development of HIV IHTS'

One of the key arguments made in the paper 'Consumer activism in HIV pharmacology' was the general absence of, yet potential for, affected community involvement in the development of HIV IHTs. While it is apparent that voluntary sector groups are involved in ongoing dialogue with pharmaceutical manufacturers and many receive funding from such manufacturers to produce treatment information for users, the suggestion that they might also be proactive in the design of therapeutic initiatives was received by the seminar audience as novel. Yet, this same audience was well informed of the merit of such work in the history of the epidemic. Political activism for treatments is frequently acknowledged as having achieved exemplary results in bringing about the current gains in HIV prevention and, now, medically driven viral suppression. It is the achievement of medical innovations that led Stephen Epstein to claim that activist movements can be genuine participants in the construction of scientific knowledge (1995:409).

One of the important outcomes of the discussion following the seminar paper was that Australian voluntary sector HIV organisations function in very similar ways to those in the UK. They too provide treatment information and liaise with pharmaceutical companies for this purpose. However, it was also clear that Australian organisations do not have the same level of access as those in the UK to international pharmaceutical manufacturers. The access of UK organisations is particularly strong due to their linking with other European voluntary sector networks (for example: European Community Advisory Board or ECAB). Nevertheless, the smaller, more collaborative and highly structured nature of the Australian voluntary sector (organisations do not compete against each other for funding) provides evidence of the potential for this sort of activism. For example, the Australian Federation of AIDS Organisations, along with the NCHSR, is a key member of the consortium involved in undertaking vaccine trials in Australia. It currently participates in the design of HIV vaccine protocols and in the HIM study, cited above. The two contrasting voluntary sector contexts provide a valuable comparison for further investigating user involvement in the field of HIV. Such an investigation could also have relevance to issues of patient involvement now being promoted in the UK (DH, 2001, Novas and Rose 2000).

Topic C: 'HIV Genomics Research'

Although, as Webster (2002:446) points out, genomics has 'begun to redefine the scale, scope and boundaries of the medical portfolio itself,' the significance of genomics or even post-genomics for HIV management or eradication remains largely ignored. The reasons for this are not clear. Historically, HIV medical science is an area that has undergone radical transformation and perhaps more so than most other

areas of disease. In the view of Brotherton (2003 per comm.), past achievements and their consequences may have come to occupy the attention of those living with and/or working with HIV in such a way that it prevents consideration of other scientific innovations. Voluntary sector/consumer representative organisations and researchers in the field (with the exception of vaccine research) are now, seemingly, taken up with the effects of current pharmaceutical interventions. Yet, it is also apparent, that the highly toxic effects of the drugs and their increasingly apparent side effects noted in the current UK study (Flowers, et al, 2002; Rosengarten, In press), by Race and Wakeford (2000) and by Persson (2002), cast doubt on the viability of current drug regimes for the long term management of HIV.

A collaboration to study the implications of HIV genomic post-genomic research (such as DNA microarray testing to establish a genetic marker for human host infectivity) could draw on the research perspectives shared by Australian researchers and those in the UK working specifically on the social implications of genomics. It could compare and contrast the different ways in which affected communities are key players in current social research on the social implications of these technologies. Organisations appropriate to being partners in this type of research would be the Australian Federation of AIDS Organisations, the National Association of People Living with HIV Australia and the National AIDS Trust and the African HIV Policy Network, UK. The starting point for such research might be differences in community perceptions of molecular technologies. These perceptions could be considered in relation to current social research on existing HIV IHTs and the social implications of genomics more generally.

REFERENCES

- Brotherton, A (2003) personal communication.
- Department of Health (DH) Report (2001a) 'Involving Patients and the Public in Health Care: A Discussion Document,' September 2001.
- Epstein, S (1995) 'The Construction of Lay Expertise: AIDS Activism and the Forging of Credibility in the Reform of Clinical Trials' *Science, Technology, and Human Values*, Vol 20 (4) Special Issue: Constructivist Perspectives on Medical Work: Medical Practices and Science and Technology Studies, 408-437.
- ESRC (2001) *Innovative Health Technologies Research Programme*. Swindon: Economic and Social Research Council; available at: <http://www.york.ac.uk/res/ihl>
- Flowers, P., Frankis, J., Rosengarten, M., Davis, M., Hart, GJ., Imrie, J. 'The scientific construction of the HIV positive person within studies of anti-viral efficacy: a systematic and critical review.' 14th *International AIDS Conference, AIDS 2002*, Barcelona, Spain, 7 July – 12 July 2002.
- Kippax, S. (2003) personal communication.
- Kippax, S., Crawford, J., Davis, M., Rodden, P., and Dowsett, G.W. (1993) 'Sustaining safe sex: A longitudinal study of a sample of homosexual men.' *AIDS*, 7, 257-263.
- Kippax, S. and Race, K (In Press) 'Sustaining safe practice: twenty years on' *Social Science & Medicine*.
- Novas, C. & Rose, N (2000) 'Genetic risk and the birth of the somatic individual' *Economy & Society*, 29, 4: 485-513.
- Race, K. (2003) personal communication.
- Race, K (2001a) 'The Undetectable Crisis: Changing Technologies of Risk' *Sexualities*, 4:2.
- Race, K. (2001b) 'Incorporating clinical authority: a new test for people with HIV.' In Watson, N., and Cunningham-Burley, S. (eds.) *Reframing the Body*. Palgrave: Hampshire and New York.
- Race, K. & Wakeford, E. (2000) 'Dosing on time: Developing adherent practice with Highly Active Anti-Retroviral Therapy,' *Culture, Health and Sexuality* Vol. 2 No. 2 213-228.
- Race, K., McInnes, D., Wakeford, E., Kleinert, V., McMurchie, M., Kidd, M. (2002) 'Adherence and Communication' Reports from a study of HIV General Practice. Monograph 8, Sydney: National Centre in HIV Social Research.
- Race, K. & Wakeford, E. (2000) 'Dosing on time: Developing adherent practice with Highly Active Anti-Retroviral Therapy,' *Culture, Health and Sexuality* Vol. 2 No. 2 213-228.
- Rosengarten, M (In press) 'Consumer activism in HIV pharmacology' *Body & Society*.

Rosengarten, M, Race, K. & Kippax, S. (2000) "'Touch Wood, everything will be OK": gay men's understandings of clinical markers in sexual practise,' *Monograph 7/2000* Sydney: National Centre in HIV Social Research.

Slavin, S., Race, K., and Kippax, S., (1998) 'Sex Culture Project.' A report produced the Commonwealth Department of Health and Family Services, National Centre in HIV Social Research, University of New South Wales, Australia

Van de Ven, P., Kippax, S., Crawford, J., Rawstorne, P., Prestage, G., Grulich, A., and Murphy, D. (2002) 'In a minority of gay men, sexual risk practice indicates strategic positioning for perceived risk reduction rather than unbridled sex.' *AIDS Care*, 14(4), 471-480.

APPENDIX

List of Research Projects Discussed

Kippax, S., Kaldor, J., Race, K., Prestage, G., Crawford, J., Grulich, A., Song, A., and Grieson, J. (ongoing) 'Positive Health study.'

Race, K., Wakeford, E., and Kippax, S (1998-2000) 'HIV Health in Context.'

Persson, A and Slavin, S. (in progress) 'The Side Effects Project: Living with HIV Treatment Side Effects and Body Shape Change.'

Race, K., Mc Innes, D., Kidd, M., McMurchie, M., and Moore, A. (1999-2000) 'Compliance Supportive Communication Project.'

Mao, L., Van de Ven, P., Prestage, G., Fengyi, J., Grulich, A., Crawford, J., Kippax, S., Murphy, D., and Allan, B (in progress) Health In Men.

Publications and Reports Reviewed

Kippax, S. and Race, K (In Press) 'Sustaining safe practice: twenty years on' *Social Science & Medicine*.

Race, K. (2001a) 'The Undetectable Crisis: Changing Technologies of Risk.' *Sexualities*, 4:2, 167-189.

Race, K. (2001b) 'Incorporating clinical authority: a new test for people with HIV.' In Watson, N., and Cunningham-Burley, S. (eds.) *Reframing the Body*. Palgrave: Hampshire and New York.

Kane Race, David McInnes, Elizabeth Wakeford, Veronica Kleinert, Marilyn McMurchie, Michael Kidd (2002) 'Adherence and Communication' Reports from a study of HIV General Practice. Monograph 8, Sydney: National Centre in HIV Social Research.

Race, K. & Wakeford, E. (2000) 'Dosing on time: Developing adherent practice with Highly Active Anti-Retroviral Therapy,' *Culture, Health and Sexuality* Vol. 2 No. 2 213-228.

Persson, A. (2002) 'Three Bodies of Lipodystrophy: A Theoretical Exploration of Body Shape Change' *The HIV/AIDS, Hepatitis and Related Diseases Social Research Conference*, University of New South Wales, Sydney, 28 May 2002