



ashm
Australasian Society for HIV Medicine

Proceedings Report

Australian HIV Antiretroviral Guidelines Consensus Discussion

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Background to the Antiretroviral Guidelines Consensus Discussion

The annual Antiretroviral Guidelines Consensus Discussion is designed as a forum to examine issues of importance arising from the USA Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents HIV-1 Infected Adults and Adolescents. These guidelines have been endorsed by Australia and form the basis on which the Australian commentary is developed. The Australian commentary to the latest Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents is available at www.ashm.org.au/aust-guidelines. The Antiretroviral Guidelines panel has been given the responsibility of updating a commentary to these guidelines to ensure they are appropriate for and applicable to Australia and are kept up to date. This activity is managed by the Australasian Society for HIV Medicine (ASHM). The Panel uses information, discussion and debate from the annual Antiretroviral Guidelines Consensus Discussion to inform this commentary. The Guidelines (including Australian commentary) and a list of current Panel members are available on the ASHM website at <http://www.ashm.org.au/aust-guidelines>.

Summary of Key Findings

The majority of feedback was very positive. Attendance was high and comparable to that of 2008. A total of 295 delegates attended either one or both sessions. GPs comprised of 46% of total delegates. Survey response rate was 41%. Delegates found the presentations of a high quality and noted there was sufficient opportunity for audience participation. This was an improvement on the feedback received from delegates at the 2008 ARV Consensus Discussion.

Many respondents mentioned that the consensus presentations were comprehensive and well presented. Others noted that discussions were very informative and provided practical 'best – practice' examples.

Suggestions for future focus include a discussion on renal decline among people living with HIV/AIDS, a focus on likely resistance patterns and further presentations on cardiovascular disease risk and the practical issues in prescribing antiretrovirals' in pregnancy.

Overview of 2009 Program and Presentations

The annual Antiretroviral Guidelines Consensus Discussion was incorporated into the clinical stream of the main Australasian HIV/AIDS 2009 Conference program. The 2009 Antiretroviral Guidelines Consensus Discussion was open to all registered HIV/AIDS Conference delegates including representatives of the pharmaceutical industry.

The Antiretroviral Guidelines Consensus Discussion program consisted of four presentations which were delivered by a total of four speakers and included evidence-based presentations from international and local experts on the latest research and developments in HIV treatment.

Following feedback from the 2008 Consensus Discussion which highlighted the need for greater audience participation, all delegates attending the 2009 Consensus Discussion were provided with questions cards and an opportunity at the end of each presentation to raise questions or make a comment.

A webcast of the presentations from the Antiretroviral Guidelines Consensus Discussion is available on the ASHM website at <http://www.multiwebcast.com/ASHM/2009/21st>. Continuing Medical Education (CME) activities are also available for these webcast presentations. All ASHM members and conference delegates have received a password to access the presentations.

Antiretroviral Guidelines Consensus Discussion Program

Session 1: Thursday 10 September 2009 1.30pm – 3.00pm

Topic 1: The changing nature of antiretroviral treatment failure
Dr Steve Deeks

Topic 2: Cardiovascular disease – HIV drugs vs. HIV disease
Professor Andrew Carr

Session 2: Friday 11 September 1.30pm – 3.00pm

Topic 1: Practical issues in prescribing antiretrovirals in pregnancy and in women who may become pregnant
Dr Michelle Giles

Topic 2: Should CNS penetration influence choice of an antiretroviral regimen?
Professor Bruce Brew

Session 1: Thursday 10 September, 1.30pm – 3.00pm

Session one was chaired by Dr Mark Kelly and Dr Alan Street. The first presentation was delivered by Dr Steve Deeks, an invited international speaker and member of the US Department of Health and Human Services (DHSS) Panel on Antiretroviral Guidelines for Adults and Adolescents. His topic was titled, "The changing nature of antiretroviral treatment failure."

The second speaker was Professor Andrew Carr from the Immunology/HIV/Infectious Diseases Clinical Services Unit and St Vincent's Hospital in NSW. His topic was titled, "Cardiovascular disease – HIV drugs vs. HIV disease."

Following each presentation, speakers were invited to respond to audience questions and comments.

This session concluded with the launch of *HIV Management in Australasia: a guide for clinical care*, Ed 2009.

Session 2: Friday 11 September, 1.30pm – 3.00pm

The second session was chaired by Dr Fraser Drummond and Professor Jenny Hoy, and consisted of two presentations. The first presentation 'Practical issues in prescribing antiretrovirals in pregnancy and in women who may become pregnant' was presented by Dr Michelle Giles from The Alfred in Victoria. The second presentation focused on whether 'CNS penetration influenced choice of an antiretroviral regimen?' delivered by Professor Bruce Brew, head of virology at St Vincent's Hospital, NSW.

Following each presentation, speakers were invited to respond to audience questions and comments.

Evaluation and Feedback

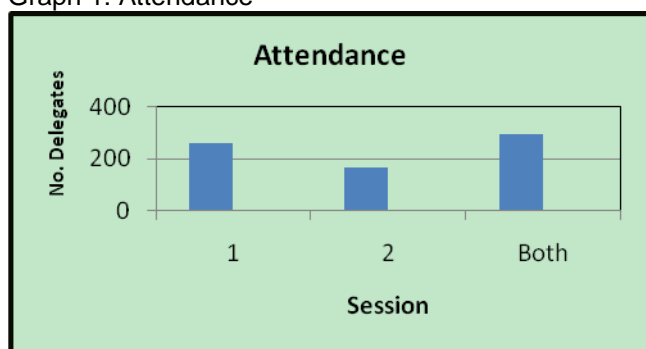
Evaluation Response

A total of 105 evaluation forms were returned after the two sessions, resulting in a 41% response rate. Three surveys were excluded from the entire analysis as sections A, B and C were incomplete. A total of 101 surveys were analysed for sections A and B. Twenty surveys did not have any data for section C and were subsequently removed from the analysis, leaving 81 survey responses for section C.

A. Attendance

The 2009 Consensus Discussion was well attended. The attendance is presented in the table below.

Graph 1: Attendance

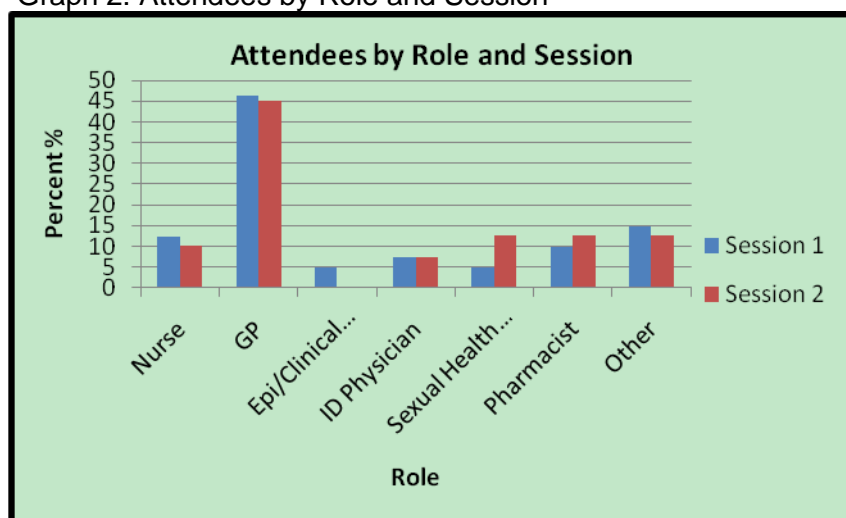


The number of delegates in graph 1 were based on the sign-in sheets. There were 257 delegates at Session 1 and 168 delegates in Session 2. A total of 295 delegates attended either one or both sessions.

Graphs 2 illustrates that sessions were largely attended by GPs. Attendance was however broadly represented by a range of health professionals, including sexual health physicians, nurses, pharmacists, social workers, registrars and students. Both community and hospital based professionals were present.

The 'Other' category included: registrars, clinical managers, social workers and students.

Graph 2: Attendees by Role and Session



Graph 3: Attendance at 2008 Consensus Discussion



Participants were asked to comment on whether they had attended the 2008 Consensus Discussion. 46% of respondents had participated in the 2008 Consensus Discussion while 54% had not been involved in 2008.

B. Sessions in the Consensus Discussion

A total of 101 surveys were analysed for this section. Responses and comments for each session are provided below. The feedback for all sessions was generally positive.

Session 1

Presentation 1: The changing nature of antiretroviral treatment failure?

Presented by: Dr Steve Deeks

Table 1

What was your experience of the session: " The changing nature of antiretroviral treatment failure?"		
Answer Options	Response Percent	Response Count
Excellent	33%	17
Good	46%	24
Satisfactory	21%	11
Poor	0%	0
	100%	52

Additional Comments

- The presentation did not include a clear summary on the current situation of HAART.
- There was need for further delineation of the patient population.

Presentation 2: Cardiovascular disease – HIV drugs vs. HIV disease

Presented by: Professor Andrew Carr

Table 2

What was your experience of the session: "Cardiovascular disease – HIV drugs vs. HIV disease?"		
Answer Options	Response Percent	Response Count
Excellent	21%	11
Good	62%	32
Satisfactory	15%	8
Poor	2%	1
	100%	52

Additional Comments

- There was no mention of the European AIDS Clinical Society (EACS) Metabolic Guidelines.
- There was a comprehensive and balanced assessment of current studies.
- The presentation was good but there was too much information. The salient points could have been better highlighted.
- This topic was well presented.

Session 2

Presentation 1: Practical issues in prescribing antiretrovirals in pregnancy and in women who may become pregnant.

Presented by: Dr Michelle Giles

Table 3

What was your experience of the session: "Practical issues in prescribing antiretrovirals in pregnancy and in women who may become pregnant?"		
Answer Options	Response Percent	Response Count
Excellent	80%	40
Good	18%	9
Satisfactory	2%	1
Poor	0%	
Total	100%	50

Additional Comments

- The presentation was practical and relevant to my setting.
- More information on co-infection would have been good.
- It was an excellent presentation. Please present at the ARV Discussion next year.
- This presentation was very valuable given the number of positive pregnant women
- This was the best presentation at the HIV/AIDS Conference this year. It was simple and easy to understand. The examples provided made it easy to put into practice.
- Excellent presentation, very comprehensive, authoritative and clear. It also generated a lot of questions which was the main aim of the session.
- Outstanding – very practical and evidence based.
- The presenter engaged the audience quite well.
- Could discuss more important issues in relation to pregnancy.
- Fantastic.

Presentation 2: Should CNS penetration influence choice of an antiretroviral regimen?

Presented by: Professor Bruce Brew

Table 4

What was your experience of the session: "Should CNS penetration influence choice of an antiretroviral regimen?"		
Answer Options	Response Percent	Response Count
Excellent	28%	14
Good	50%	25
Satisfactory	18%	9
Poor	4%	2
	100%	50

Additional Comments

- This topic was quite relevant.
- The presentation was research oriented but very informative.
- The presentation was too long and very wordy. Some slides were hard to read.
- A good overview.

Overall comments/suggestions on the 2009 Antiretroviral Guidelines Consensus Discussion

- A discussion on renal decline among PLWHA would have been useful.
- There was good audience participation.
- Very informative.
- A focus on likely resistance patterns would have been useful.
- Comprehensive, well prepared.
- The topics were helpful in maintaining 'best-practice' principals.
- Excellent.
- Additional consensus sessions would be useful.
- Panel should insist on RCTs that determine CVD risk from antiretroviral, especially Abacavir (ABC).
- Sufficient opportunity for audience participation.

C. Use of the Australian Commentary of the HIV Antiretroviral Guidelines

This section of the evaluation form has been used to supplement the online evaluation of the Australian ARV Guidelines conducted in early 2009. It includes responses from 81 surveys.

Table 5

How often do you use the Australian Commentary to the USA Department of Health and Human Services Guidelines on the Use of Antiretroviral Agents for the Management of HIV 1 Infected Adults and Adolescents available on the ASHM website?		
Answer Options	Response Percent	Response Count
Never	12%	10
1 or 2 times	44%	36
More than twice	43%	35
	100%	81

The majority of respondents (44%) had used the guidelines either once or twice and 43% had used the guidelines more than twice.

Table 6

If yes, what is your reason for using the guidelines?		
Answer Options	Response Percent	Response Count
To determine treatment regimens for patients	18%	41
To update my knowledge	32%	72
As a resource/reference tool	36%	78
For training purposes	12%	30
Other	2%	4
	100%	

Note: There were multiple responses to this question

The most common reasons for using the guidelines was 'as a reference tool' 36% followed by to 'update knowledge' 32%. 18% of respondents used it to 'determine treatment regiments for patients' and 12% used it for 'training purposes'. 2% of respondents used it for 'other' purposes but did not mention the specifics.

Table 7

How would you rate the ease of use (finding information) of the Guidelines?		
Answer Options	Response Percent	Response Count
Excellent	4%	3
Good	59%	48
Satisfactory	28%	23
Poor	0%	0
Never used the Guidelines	9%	7
	100%	81

Most respondents (59%), mentioned that the 'ease of use' of the guidelines was good. Those who thought it was satisfactory were 28%, while 4% thought that it was excellent. A total of 9% of the respondents had never used the guidelines.

Table 8

The Guidelines are currently available as a single pdf document on the ASHM website. Would you prefer if the Guidelines were available in the following formats?

Answer Options	Response Percent	Response Count
I prefer the current format	27%	28
Searchable HTML/Divided into smaller sections	34%	36
CD ROM	5%	5
Printable Booklet	27%	28
PDA download	8%	8
	100%	

Note: There were multiple responses to this question

Respondents preferred that the guidelines be made available in a range of formats. The vast majority preferred the guidelines to be available in an online format.

Table 9

Are there other groups/areas not covered by the Guidelines (eg babies/children) which require Australian commentary?		
Answer Options	Response Percent	Response Count
No	74%	60
Yes	16%	13
Not answered	10%	8
Total	100%	81

Table 10

Are there particular areas of the Guidelines that do not adequately take account of Australian practice and that need additional commentary or information?		
Answer Options	Response Percent	Response Count
No	91%	74
Yes	4%	3
Not answered	5%	4
Total	100%	81

A few respondents (4%) thought the guidelines were inadequate but did not provide any further comments as to the specific areas in need of improvement.

Table 11

Would you recommend the Guidelines to colleagues?		
Answer Options	Response Percent	Response Count
No	5%	4
Yes	85%	69
Not answered	10%	8
Total	100%	81

Table 12

Have you used any other antiretroviral Guidelines?		
Answer Options	Response Percent	Response Count
No	38%	31
Yes	62%	50
Not answered	0%	0
Total	100%	81

Over half the respondents mentioned using other antiretroviral guidelines. The most common other guideline was the British HIV Association Guidelines, followed by the European Guidelines and the Guidelines from the International AIDS Society USA.

Appendix 1: Rapporteur Report

The antiretroviral (ARV) guidelines consensus discussions were held on the second and third day of the 2009 Australasian HIV/AIDS Conference at the Brisbane Convention and Exhibition Centre. The symposium brought together one international and three national speakers to discuss the ARV guideline implications.

(1) Steven Deeks

The changing nature of antiretroviral treatment failure

Dr Deeks from the University of California (San Francisco USA) presented an update about the pending modifications to the Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents.¹ The 2009 guideline update is expected in November this year. He indicated that there should be new information on when to start, what to start (e.g raltegravir, role of abacavir) and laboratory monitoring.

Dr Deeks went into greater detail on the management of treatment-experienced patients within the new DHHS framework. Points of interest were:

- In treatment-experienced patients with suppressed viraemia, assess adherence frequently and simplify the regimen as much as possible. Change individual antiretroviral drugs to reduce or manage toxicity, as needed. The rationale for a simplification of regimens includes a reduction in pill burden, dosing frequency and improvements in quality of life
- Evaluation of antiretroviral treatment failure in a patient should include:
 - An assessment of the severity of HIV disease of the patient
 - The antiretroviral treatment history, including the duration, drugs used, antiretroviral potency, adherence history, and drug intolerance/toxicity
 - HIV RNA and CD4 cell count trends over time
 - The result of prior drug resistance testing.
- Virological failure on treatment can be defined as a confirmed HIV RNA level >400 copies/mL after 24 weeks, >50 copies/mL after 48 weeks, or a repeated detectable HIV RNA level after prior suppression of viraemia.
- Drug resistance testing should be obtained while the patient is taking the failing antiretroviral regimen (or within 4 weeks of treatment discontinuation) (AI).
- The goal of treatment for patients with prior drug exposure and drug resistance is to re-establish maximal virological suppression, HIV RNA <50 copies/mL (AI).
- Use the treatment history and the past and current resistance test results to identify fully active agents to design a new regimen (AII). Adding at least two or preferably three fully active agents to an optimized background antiretroviral therapy (ART) regimen can provide significant antiretroviral activity (BII).
- Immunologic failure can be defined as a failure to achieve and maintain an adequate CD4 response despite virological suppression.
- For immunologic failure, current medications, untreated coinfection, and serious medical conditions should be assessed.

Dr Deeks pointed out that there continues to be no consensus for when and how to treat immunologic failure. Assessing and managing a patient who has antiretroviral experience, who exhibits drug resistance, and who is experiencing treatment failure is complex and expert advice is critical.

There will be format changes to the updated guidelines, which will include a more continuous flow in the content, all tables will be grouped together, and the references for the entire document will be at the end of the manuscript while relevant references will be at the end of each section. The appendix will contain larger tables and all tables will be available in a PDF format.

(2) Andrew Carr

Cardiovascular Disease – How should it affect antiretroviral therapy?

Dr Carr from St Vincent's Hospital (Sydney, Australia) presented an overview of the epidemiology, biomarkers and DHHS guidelines/Australian commentary and recommendations for HIV and cardiovascular disease (CVD).² He presented data from a number of studies including the D.A.D

study, the French Hospital Database, the VA cohort, the STEAL study for the risk of myocardial infarction (MI) by non-nucleoside reverse transcriptase inhibitors (NNRTI) and protease inhibitors (PI) exposure. Discussions centred on the impact that risk of CVD has had on the types and timing of ART for over 10 years. He presented data from cohort studies, which suggest that CVD is more likely with lower CD4 cell counts, and in patients receiving some PI, Abacavir (ABC) or didanosine (ddl). He pointed out that we believe PIs cause CVD because PIs adversely affect lipids but half the CVD association of PIs appears unrelated to lipid levels. Also the current use of ABC/ddl is associated with MI in some studies, but no mechanism has been proven and bias has not been fully addressed at this point.

The DHHS guidelines/Australian commentary provides a recommendation about avoiding ABC if the patient is at a high CVD risk, but there were no similar recommendations for avoiding PIs. Dr Carr suggested that this needed to be addressed in the future.

He also pointed out that NNRTI were not associated with CVD; although EFV and ritonavir boosted lopinavir (rLPV) have identical lipid effects.

The nucleoside reverse transcriptase inhibitors (NRTI) Zidovudine/stavudine (ZDV/ d4T) cause dyslipidaemia and insulin resistance but were not associated with CVD. The reason for this continues to unclear.

Although many CVD biomarkers are under evaluation, only total and HDL cholesterol have been shown to predict CVD. The best predictor of CVD in a person with HIV infection is the Framingham equation; this emphasises the importance of combining all CVD risk factors – smoking, older age, male sex, hypertension, dyslipidaemia and diabetes.

Most ART-naïve patients are not at high CVD risk, but many more older, ART-experienced patients may be at risk. ART choice is influenced by many factors apart from CVD risk and these require equal consideration.

Dr Carr discussed the DHHS/Australian commentary on HIV CVD in detail. The relevant issues pointed out during his presentation are listed below:

- Several large observational studies have indicated that the risk of several non-AIDS-defining conditions, including cardiovascular diseases is greater than the risk for AIDS in persons with CD4 cell counts >200 cells/mm³; the risk for these events increases progressively as the CD4 cell count decreases from 350 to 200 cells/mm³
- In SMART, the risks for all-cause mortality, which was largely attributed to several non-AIDS defining conditions (including cardiovascular disease) were greater in participants randomized to CD4 cell count-guided treatment interruption than in those who received continuous therapy
- Conflicting data exist regarding ABC and CVD
- Table 5b - Potential Benefits of Early Therapy include decreased risk of non-opportunistic conditions, including cardiovascular disease
- Although conflicting data exist, ABC-3TC has been moved to an alternative dual-NRTI component because of concerns regarding an increased risk of myocardial infarction in patients with high cardiac risk
- Use ABC with caution in the presence of the following:
 - HIV RNA $>100,000$ copies/ml - higher rate of virological failure in ACTG 5202,
 - High risk for cardiovascular disease

From the DHHS Recommendations there are several factors to consider when selecting initial ART including co-morbid conditions (e.g. CVD, chemical dependency, liver disease, psychiatric disease, renal diseases, or tuberculosis), potential adverse drug effects, potential drug interactions with other medications, pregnancy or pregnancy potential, genotypic drug resistance, gender and CD4 cell count if considering nevirapine, HLA-B*5701 testing if considering ABC, patient adherence potential and convenience (pill burden, dosing frequency, food/fluid considerations).

The recommendations from the Australian ARV Panel Commentary on DHHS CVD

- The decision about ABC in initial combination therapy as an alternative rather than a preferred agent is based on two observations, potency and CVD.
- Retrospective analyses of D:A:D and SMART have shown that patients receiving ABC are at an increased risk of myocardial infarction however keep in mind that:
 - Patients not treatment naïve
 - Patients not randomised to receive ABC, so the possibility of channelling bias cannot be excluded
 - Patients in SMART were treatment-experienced and many had pre-existing risk factors for CVD”
- The decision on which NRTI backbone to use should be made after evaluating CVD risk and considering baseline HIV viral load

(3) Michelle Giles

Practical issues in prescribing antiretrovirals in pregnancy and in women who may become pregnant

Dr Giles from the Alfred (Melbourne, Victoria) started her presentation by posing a number of questions to consider for the use of antiretrovirals in women infected with HIV, during pregnancy and in women considering pregnancy.³ For non-pregnant woman of reproductive potential the issue is: What should be the first line regimen? If the woman is starting antiretrovirals in pregnancy then it is important to ask: Which drugs do you use? When do you start?

On the subject of continuing ART in pregnancy Dr Giles suggested that there is the need to ask: Should you switch ART regimens? Do you still need to use intrapartum zidovudine? And then there is the issue of post partum and the obvious question is: What do you do with the ART post partum?

In the case of women who do not want children or who wish to delay this but who require antiretroviral therapy it is important to provide safe, effective contraception. The choice of this is influenced by other medical conditions (including gynaecological), the HIV status of their partner, ability to negotiate consistent condom use and drug interactions, particularly with antiretrovirals.

On the other hand Dr Giles pointed out that women who wish to become pregnant the choice of antiretroviral regimen must take into account safety data during pregnancy, past antiretroviral exposure, side effect profile and pharmacokinetic changes related to pregnancy. Additional issues to consider include the optimal time to start antiretrovirals, whether to switch if the woman is on an effective combination not containing zidovudine and the choice of regimen if prescribed only to prevent perinatal HIV transmission.

It is generally accepted that an assessment of reproductive intent and sexual activity should be incorporated into routine care for women infected with HIV. This will inform the choice of ARTs and contraception (if required). Zidovudine/lamivudine/lopinavir/ritonavir should be considered if the woman is actively trying to conceive. There is a requirement to avoid efavirenz if there is a high pregnancy potential.

Women receiving combination antiretroviral therapy (cART) and become pregnant continue ART regimen if it is successfully suppressing viraemia while avoiding potentially teratogenic drugs. It will be important to discuss switching to ZDV containing regimen but not if this will compromise adherence or virological control. The cessation during first trimester (1stTM) not recommended.

In women who are ARV naïve and have indications for therapy there is a need to consider resistance testing, to void EFV in the 1stTM, use ZDV when feasible and to start 1stTM if immediate initiation required for maternal health.

In a woman who is ARV naïve and does not require treatment for her own health it is recommended to start cART after the 1stTM (earlier probably better), use ZDV when feasible, ZDV monotherapy is controversial but an option in women with low viral load who want to limit fetal drug exposure, triple NRTI (ZDV/3TC/ABC) to be considered because of known PK profile and published data on acceptable toxicity data during pregnancy. It is important to remember the half-life of different drugs when stopping. If the woman is on a NNRTI regimen consider continuing the NRTIs for 7 days.

There is limited data and the exact duration is not clear. There is also no available data to guide the choice of ART regimen in subsequent pregnancies.

(4) Bruce Brew

Should CNS penetration influence the choice of an antiretroviral regimen?

Dr Brew from St Vincent's Hospital (Sydney, NSW) reviewed the biological nature of HIV replication in long-lived cells such as perivascular macrophages, microglia and astrocytes.⁴ He provided evidence from clinical, cerebrospinal fluid, and neuropathological data to support his discussion. There is a significant volume of data that suggests the central nervous system (CNS) is a sanctuary site. The evidence comes from studies of the cerebrospinal fluid (CSF) comparing HIV RNA in CSF vs. the blood with higher levels in the former. Other studies have shown different ART resistance patterns in CSF. Clinical studies have also indicated the development of varying degrees of dementia/neuropsychological impairment despite plasma viral load suppression. Animal model studies have provided evidence for the CNS as a sanctuary site, for example, Simian Immunodeficiency Virus infected rhesus macaques have persistent viral DNA in the brain. Dr Brew pointed out that there is debate over the power of some studies.

Antiretroviral drugs vary in their ability to cross the blood-brain barrier and further differ in their ability to inhibit productive infection in brain cells. It is therefore biologically plausible that patients with HIV brain infection should have better outcomes if they are treated with antiretroviral drugs with good CNS penetration (neuro-HAART) than those who are not (non neuro-HAART). Neuro-HAART is defined as three or more penetrating ARVs with a revised CPE score of 4 or more.

Dr Brew pointed out that presently there is no evidence available for the prophylactic use of neuro-HAART as an initial/second line regimen. Long-term there could be a danger of resistance and thus using up neuro-effective ARTs earlier than necessary. Neuro-HAART should be considered for patients with HIV related cognitive impairment (AII). In terms of a third line/salvage regimen the same recommendations as indicated above apply. Neuro-HAART is moderately recommended if predictive markers are present and patient has advanced HIV disease (BIII). In patients at risk of cognitive impairment neuro-HAART should also be used.

The PowerPoint and Webcast presentations for these lectures are available from the ASHM website (<http://www.ashm.org.au>).

**Rapporteur Report by Paul McQueen
Technical Writer
ASHM**

References

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- (4) Brew BJ, Cysique L. Should CNS penetration influence the choice of an antiretroviral regimen? 21st Annual Conference of the Australasian Society for HIV Medicine, September 9 -11 2009; Brisbane. Abstract 582:162