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Efficiency of Interventions in HIV Infection, 1994–2004

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Abstract

The pandemic caused by HIV is one of the fastest growing health problems in the world today. Given the limited resources available to healthcare systems in many of the most heavily affected countries, it is crucially

important to know the effectiveness, efficiency, equity, and acceptability of the interventions being implemented to contain this pandemic. This review examines the peer-reviewed literature on the efficiency of prevention, treatment and care interventions published between 1994 and 2004, findings reported by these studies, and methods used. The results varied by geographical setting and population studied.

Some interventions were clearly cost effective including: prevention efforts and testing programs among vulnerable populations; blood screening in high-income nations and in sub-Saharan Africa; providing antiretroviral drugs and other interventions to expectant mothers and infants; treating certain opportunistic infections; and providing combination anti-retroviral therapy. However, most studies were set in the US, while only one in six dealt with sub-Saharan Africa. Few studies could be identified from continental Asia and none from Latin America. Three-quarters of all papers focused on hospital or primary care settings, with only prevention studies regularly evaluating community-based interventions. There is a paucity of primary data and thus, outcomes or costs were frequently modeled, using data from multiple sources in the absence of context-specific data.

Establishing multicenter prospective monitoring systems on the use, cost and outcome of HIV service provision in middle and lower income countries may provide data to fill some of the large gaps which exist in the literature on interventions in these countries. The resulting gaps in the current scientific literature limits the ability for it to guide policy makers in those settings where the epidemic is most intense. Increased research in such settings and dissemination of their findings is urgently required, especially given the need for intensified prevention strategies to complement the scaling up of HIV treatment and care services in these countries.

The pandemic caused by HIV is one of the greatest public health threats in the world today. It is estimated that 28 million are thought to have died of the illness by December 2004, while another 40 million HIV-infected people were alive.[1] Almost 5 million people are thought to have been infected during the previous 12 months. The majority of the disease burden remains in sub-Saharan Africa, but the number of HIV-infected people is rapidly increasing in other regions, especially in Asia and Eastern Europe.

HIV is predominantly transmitted sexually, but other routes of transmission include parenteral transmission – through infected blood, blood products or injecting drug use – and vertical transmission from mother to child (MTCT), which may occur before, during, or after birth. Although the complementary nature of preventing new HIV infections and treatment and care of HIV-infected individuals was recognized some time ago,[2] only recently has it been more widely recognized that the containment of the HIV pandemic requires a global strategy which combines effective prevention with treatment and care programs.[3] The increased provision of HIV treatment, care and prevention services to millions of HIV-infected people has now become a major policy target among national and international organizations across the world. WHO and UNAIDS (Joint United Nations Program on HIV/AIDS) are now implementing the '3 by 5' program, first announced at the Barcelona 2002 World AIDS Conference[4] with the aim of scaling up HIV treatment and care, including antiretroviral therapy, in middle and low income countries for three million HIV-infected individuals by the end of 2005. This is estimated to be 50% of the HIV-infected people in the world who require such services.

Although this is an emergency response, to be successful in the longer term such programs must be biomedically, economically, socially, and politically sustainable, and need to strengthen local health services. The success of these programs needs to be assessed in terms of their effectiveness, efficiency, and equity of coverage as well as acceptability to both users and providers.[5] Effectiveness in this context refers to the outcome of interventions in real life situations; efficiency focuses on the level of resources required to achieve an outcome; equity considers the distribution of benefits from the intervention or program; and acceptability can refer to the intervention being acceptable to users and providers, or the quality of life improvements achieved through it.[5] This is particularly important given the limited resources available in those countries most affected by the pandemic.[5]

Although all four criteria are important, this paper reviews only the literature on the efficiency of HIV-related interventions, published in the Anglo- or Francophone scientific literature. The studies cover HIV prevention, HIV testing and blood screening, MTCT, and HIV treatment and care including antiretroviral therapy (ART) and opportunistic infections (OIs). The literature was evaluated using two criteria: (i) the topics covered and (ii) the methodological strength of the studies, where this strength was judged on the type of data used, the clarity of the explanation provided, and the degree of certainty with which the results were presented.

Although most literature reviews to date have focused on interventions of particular types, or in certain geographic areas, this paper tries to provide a broad overview of the literature published between 1994 and 2004. This allows for the identification of topics that have been well studied and those that have been neglected during this period. It also permits comparisons of the

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relative efficiency and practicability of the full range of interventions and methodologies to be made.

1. Economic Analysis

The key underlying principle of any economic analysis is the concept that using resources in one setting necessarily prevents them being used elsewhere, which is referred to as the 'opportunity cost' of the intervention. For example, should we spend resources on building a new hospital, these resources cannot then be spent on renovating existing hospitals. While building new hospitals can provide benefits through new and improved services, the opportunity cost of this course of action comprises the additional benefits foregone, which would have been created through the improvement of services at existing sites. The desire to maximize outcomes makes consideration of opportunity costs essential.

Economic analyses should also aim to provide information that will allow policy makers to evaluate the sustainability of programs. Cost studies provide information on the cost or affordability of a particular program or intervention. Studies of the efficiency of interventions or programs on the other hand provide information on the relative costs and benefits of a new intervention or program, compared with existing alternatives.[5]

Three methods are commonly used to study the efficiency of new interventions or programs: (i) cost-effectiveness analyses; (ii) cost-utility analyses; and (iii) cost-benefit analyses.[6] In cost-effectiveness analyses, costs are linked to a biological outcome, and the monetary resources required to achieve a unit of this outcome are evaluated. A commonly used outcome in studies assessing treatment and care is the number of life-years gained (LYG), whereas in preventive interventions, cases or infections averted are frequently used. While conceptually simple for most professionals to understand, difficulties may arise when one has to compare different programs using diverse outcome measures. For example, comparisons between the cost effectiveness of treatment and preventive programs to date have been difficult because of the different outcome measures used.

To address this problem, some health economists promoted the use of cost-utility analyses, where patient health states are given utility weightings that are used to determine the number of LYG through the intervention, adjusted for their quality of life. Costs are then linked to these adjusted outcomes, and instead of having to compare LYG with 'cases averted', comparisons can be made in terms of 'cost per adjusted life-year'. This method thus provides comparability across diseases or intervention categories, but often relies on quality-adjusted life-years (QALYs), which are based on the preferences of specific individuals from a particular culture at a single point in time. In addition, some professionals question whether complex disease states can be really reduced into a single numerical figure between 0 and 1. A second, very similar, cost-utility analysis outcome measure promoted in recent years by WHO is the disability-adjusted life-year (DALY).[7] This measure focuses on the ability of patients to perform various daily activities, while the QALY takes a somewhat more subjective approach, also valuing mental well-being.[8]

Some policy makers, including ministers of finance and treasury officials, would like to compare the impact of programs from different government departments, where intervention outcomes cannot be measured in terms of QALYs or other disaggregated measures. In this situation cost-benefit analyses are used, where the outcome of the intervention or program is also expressed in monetary terms. This approach allows for the impact of these interventions to be estimated across highly diverse settings, however translating biological or other outcomes into monetary terms can also be problematic.

Two other methodologies are sometimes used to assess the relative costs and benefits of an intervention. Cost-minimization analyses are a specific form of cost-effectiveness analysis or cost-utility analysis, involving interventions of similar effectiveness but different costs, and seeking to find the least expensive way to achieve the outcome. Threshold analyses, on the other hand, focus on determining how much an intervention would need to cost in order to be cost saving or cost effective, given that the outcome of that intervention is known. Neither cost-minimization analyses nor threshold analyses were included in this review.

Common to all these measures of efficiency is that they ask what improvement in outcome is found for the cost of the intervention or program. This can be measured in terms of the absolute cost and outcome gain of an intervention – comparing it with no intervention – which produces an absolute cost-effectiveness ratio, or in terms of the change in cost and outcome of a new intervention relative to an existing one, which produces an incremental cost-effectiveness ratio (ICER). It is important to be aware which comparison is being made in a given study in order to understand what the result means. For brevity, the exact nature of the comparison made is not always specified in the text of the present article, while full details of all comparisons cited are provided in the tables.

The lower the cost-effectiveness ratio, the more efficient the new intervention can be considered to be. This cost effectiveness may be measured relative to other interventions ('*X* is more or less cost effective than *Y*'), or relative to a generalized cut-off based on the values and norms operative in a particular society ('*X* is cost effective in the US'). This cut-off at which an intervention may be considered 'cost effective' should reflect what a given society is willing to pay for a particular policy at a particular point in time, but is often an arbitrary figure. In the US, it has been argued that interventions with ratios of less than $US50 000 per QALY are usually considered cost effective, and those with ratios of over $US180 000 per QALY rarely are.[9] In the UK, the National Institute for Clinical Excellence (NICE) uses a cut-off point of

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£30 000 ($US48 990) per QALY or other outcome measure.[5] Such cut-off points can become unreasonably rigid however – for example, in Canada a cut-off of $Can20 000 ($US14 270) was suggested in the early 1990s and is still being quoted today.[10,11]

For middle- and low-income countries,[12] a number of additional cut-off points have been suggested over the last decade. In the 1993 World Development Report[13] it was suggested that interventions with a cost of less than $US50 per DALY saved could be considered highly cost effective. The Commission on Macroeconomics and Health recently suggested that any intervention with a cost per DALY below the per capita income of a region should be considered highly cost effective.[14] Finally, some economists have suggested a cut-off of twice the per capita income of a country per outcome measure for those middle or lower income countries which do not have accepted cut-off points.[15]

2. Literature Search Methodology

To be included in this review, articles had to have been peer-reviewed and published in English or French since 1994 and contain an analysis of costs linked to outcomes for an HIV-related intervention. Articles published prior to 1994 were included where their subject matter remained relevant. Papers dealing with voluntary counseling and testing (VCT), treatment and prophylaxis of OIs, community interventions to reduce high-risk behaviors and some blood screening programs, were reviewed. Studies published before 1994 dealing with compulsory HIV testing, contact notification programs, and prophylaxis or treatment of HIV with zidovudine monotherapy, were excluded. The cut-off of 1994 was chosen to include the period during which a combination of antiretroviral drugs were starting to be used for HIV treatment. The final database search was performed in March 2005.

For the review, the following databases were searched: American College of Physicians Journal Club, AIDSline, Cochrane Controlled Trials Register, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effectiveness, Econlit, HealthSTAR and MEDLINE using the keywords: 'HIV', 'HIV-1', 'HIV-2', 'HIV-seropositivity', 'HIV infections' or 'AIDS', and 'cost-benefit analysis', 'cost-effectiveness analysis', 'cost-utility analysis' or 'cost-minimization analysis'. Following up additional references found in original studies or other review articles augmented these searches. Twenty-three review articles[16-38] on the cost effectiveness of HIV-related issues were identified and their references were used to check that no papers were missed by the search.

The search included studies relating to adults, adolescents, and children. While there were numerous articles based on studies in adults or adolescents, with the exception of those dealing with MTCT, only one efficiency study relating to children was found. The studies were divided into five broad categories, which included:

1. HIV prevention studies;
2. testing of patients or screening of blood for HIV infection;
3. prevention of MTCT;
4. prophylaxis or treatment with ART and related issues;
5. prophylaxis or treatment of opportunistic infections.

Each study was assessed using 19 criteria (table I) to ensure consistency across the reviews. These criteria also provided a guide in evaluating the methodologic strength of the studies, particularly in terms of collection and manipulation of cost and outcomes data. The results section discusses the main results for each study.[1]

Each study was evaluated according to their perspective: when the study considered only costs directly relating to the intervention being performed, it was considered to have a program perspective; if it included other healthcare costs not directly attributable to the intervention, it was considered to have a healthcare system perspective; if it included lost productivity or other non-healthcare costs it was said to have a societal perspective. It should be noted that all studies were assessed in terms of their specific geographic, institutional and temporal context. The settings in which the studies took place were varied; some studies were conducted in a hospital environment, while others took place in the community, and some were school- or prison-based. The context of the study affected both the costs and benefits that were found, and studies that failed to take a specific setting into account when modeling the impact of an intervention were likely to be less robust than those that did. Costs reported in the text were converted into US dollars, using 2004 conversion rates, in addition to the original currency used in the study.

Finally, based on the criteria in table I, all studies included in the review were independently scored by two of the authors (GH and EJB) to assess their methodologic strength and to reduce intra- and inter-observer variability. Studies for which the scores differed by more than four points were re-scored together by these authors. Scores for the studies in the five study categories were aggregated and for each category the mean score and 95% confidence intervals (CIs) calculated.

A total of 1172 references were found. Of these, 191 articles matched the inclusion criteria and fell into five broad categories (table II). Forty-three (23%) articles dealt with interventions carried out, entirely or in part, in the community. Twenty-one articles published prior to 1994 were not reviewed.[39-59] The articles were sorted into the five categories listed in section 2 and subdivided within those categories into different types of interventions.

1 Aspects to which these results were particularly sensitive are reported in supplementary tables I–V (tables I–V suppl.), which are published as supplementary material and are available at http://www.adisonline.com/dmo.

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Table I. Assessment criteria and scores used in evaluating the studies reviewed[a]

Criteria			Score[b] (maximum)
1	Peer-reviewed article		1 (1)
2	Model-based analysis		1
	RCT or observational study		2 (2)
3	Total sample size	Under 100	1
		Over 100	2 (2)
4	Co-morbidity controls used		1
	Patients' age considered		1
	Patients' gender considered		1
	Patients' ethnicity considered		1
	Other patient criteria considered		1 (5)
5	Cost perspective taken	Patient	1
		Program	2
		Healthcare system	3
		Societal	4 (4)
6	Cost reference year provided		1 (1)
7	Cost methodology used	Variable costs only	1
		Fixed and variable costs	2 (2)
8	Nature of cost data used	Estimates	1
		Charges	2
		Cost-adjusted charges	3
		Actual costs	4 (4)
9	Cost collection mechanism used	Multi-source	1
		Single site	2
		Multiple sites	3 (3)
10	Cost data broken down		1 (1)
11	Cost and utilization data from outcomes study		1 (1)
12	Outcomes measures used	Individuals seen	1
		Cases detected	2
		LYG; cases averted; QALYs; DALYs; CBA	3 (3)
13	Timing of outcomes data collection	Retrospective	1
		Prospective	2 (2)
14	Outcomes collection mechanism used	Multi-source	1
		Single site	2
		Multiple sites	3 (3)
15	Empirical source of effectiveness data		1 (1)
16	Empirical source of quality-of-life weights		1 (1)
17	Nature of sensitivity analysis conducted	Univariate	1
		Multivariate	2 (2)
18	Statistical methods used		1 (1)

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Table I. Contd

Criteria		Score[b] (maximum)
19	Confidence intervals used	1 (1)
20	Discount rate used	1 (1)

a Studies were assessed by criteria to ensure consistency across the reviews and to also provide a guide in evaluating the methodologic strength of the studies, particularly in terms of collection and manipulation of cost and outcomes data.

b Each study could potentially score a maximum of 41 points. A score of 0 for a given question indicated either that the article did not consider the matter or that insufficient information was provided to allow a judgment to be reached. Question 16 was only relevant if the study was a cost-utility analysis.

CBA = cost-benefit analysis; **DALY** = disability-adjusted life-year; **LYG** = life-year gained; **QALY** = quality-adjusted life-year; **RCT** = randomized controlled trial.

3. HIV Prevention Studies

A total of 38 articles dealt with adolescent and adult prevention studies (see table I suppl.).[61-98] These comprised studies on injecting drug users, other vulnerable populations, and general populations.

3.1 Interventions to Reduce Unsafe Injections

Seven studies dealt solely with injecting drug users, while a further two papers considered the impact of improving syringe policies in hospital settings. Villari et al.[61] looked at needle exchange programs in Italy, and found a very low cost-effectiveness ratio of $US1040 per LYG. Holtgrave et al.[62] modeled a needle exchange program in the US to be cost-saving from a healthcare system perspective until coverage rose above 80% of the population. Models by Laufer[63] and by Gold et al.[64] both suggested that needle exchange programs were cost-saving from a healthcare system perspective. A Canadian observational study by Jacobs et al.[65] found that over the first year of its life the cost of a needle exchange program was $Can9537 ($US7328) per case averted, while Kumaranayake et al.[66] found a program including needle and information provision in Svetlogorsk, Belarus, to cost $US359 per case averted.

Studying the impact of methadone maintenance in reducing HIV infection, Zaric et al.[67] found that regardless of the seroprevalence rates associated with injecting drug use, such programs provided considerable benefits both to injecting drug users and to the general population, with a cost-effectiveness ratio of $US8200–10 900 per QALY saved.

Laufer and Chiarello[68] reported that various needle stick-prevention devices provided protection at a cost of between $US790 and $US1574 per injury averted in a US hospital setting. Dziekan et al.[69] examined the benefits of worldwide single-use syringe provision and education, and reported that in every region of the developing world the cost per DALY of the program was lower than the region's average annual per capita income.

3.2 Interventions in Other Vulnerable Populations

Four studies considered interventions among women at increased risk of HIV infection. Two US-based studies were derived from randomized trials in a community setting. Chesson et al.[70] found condom skills training, although not other skills training (such as communication skills [negotiating] and general educational skills [knowledge surrounding HIV]), to be cost-saving among vulnerable women attending an urban health clinic. Holtgrave and Kelly[71] reported that condom skills training had a cost-effectiveness ratio of $US2024. Using survey data and literature-based assumptions, Moses et al.[72] found that treating sexually transmitted diseases (STDs) and increasing condom use among sex workers in Nairobi, Kenya, cost just $US12 per case averted on a program basis, including infections avoided both by clients and by their sexual partners. Marseille et al.[73] reported that a distribution program to provide female condoms for sex workers in Mpumalanga, South Africa, had a low cost-effectiveness ratio, and was cost-saving from a healthcare system perspective.

Observational studies among men who have sex with men were studied by Pinkerton et al.,[74] Kahn et al.,[75] and Tao and Remafedi.[76] The first two papers found that interventions focusing on lowering risk behavior were cost-saving from a healthcare system perspective. The third reported that a personalized counseling and risk-education intervention cost $US6180 per QALY saved from a healthcare perspective, but that it was cost-saving if lost productivity costs were included. Using data derived from a randomized trial, Holtgrave and Kelly[77] and Pinkerton et al.[78] reported that skills and behavior education were cost effective from a program perspective and cost-saving from a healthcare perspective.

Johnson-Masotti et al.[79] and Pinkerton et al.[80] studied randomized trials involving mentally ill adults and found relatively high cost-effectiveness ratios for group risk-reduction interventions – from approximately $US40 000 to $US136 000 per QALY. Both also reported substantial differences in response to the intervention by gender: in one case women were marginally re-

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Table II. Summary statistics for studies of interventions in HIV infection from 1987 to 2004

Study parameters	Prevention	Screening and testing	MTCT	ART	OI treatment	Total[a]
Total number of articles	38	46	35	45	28	192
Number of articles that included lifetime treatment costs[b]	27	26	29	26	16	124
Publication period						
1987–93	2	14	0	2	3	21
1994–6	5	14	6	3	2	30
1997–9	11	7	11	18	18	65
2000–4	20	11	18	22	5	76
National setting						
US	24	28	17	26	21	116
European high income	2	9	4	13	3	31
other high income[c]	3	1	2	4	3	13
middle income Africa	1	1	5	2	0	9
low income Africa	6	7	6	0	1	20
other low/middle income[d]	2	0	1	0	0	3
Intervention setting						
hospital or primary care	5	36	35	41	28	145
community[e]	27	5	0	2	0	34
both hospital/primary care or community	6	2	0	1	0	9
other	0	3	0	1	0	4
Primary source of outcomes data						
observational study	9	16	2	11	2	40
randomized trial	11	1	0	8	2	22
published literature	18	29	33	26	24	130

a One article is included in both the MTCT and ART treatment sections of the review.[60] Its features are thus represented twice in this table.

b In prevention studies, lifetime costs reflect costs from infection and are usually presented as a single figure; in treatment studies these costs generally reflect specific event costs as entered into Markov models.

c Includes papers from Canada, Japan, and New Zealand, and articles covering more than one category.

d Includes a paper from Mexico, one from Belarus, and two covering more than one category.

e Includes freestanding STD clinics.

ART = antiretroviral therapy; **MTCT** = mother-to-child transmission; **OI** = opportunistic infection; **STD** = sexually transmitted disease.

sponsive to risk reduction interventions;[79] in the other, men did not change their behavior at all.[80]

Five other studies assessed the impact of programs for vulnerable populations. Sweat et al.[81] studied a randomized trial of an education program for African-American and Latino attendees of STD clinics. Wang et al.[82] examined the economic outcomes of a school-based STD- and pregnancy-prevention program in a randomized trial of sexually-active adolescents. Heumann et al.[83] looked at an observational study of referrals provided to vulnerable uninfected adolescents for HIV prevention. All three found that the programs under study were cost-saving for the healthcare system. Pinkerton et al.[84] found an intervention among African-American male adolescents to cost $US57 327 per QALY when applied to all clients, but only $US28 455 per QALY when restricted to those who were sexually active at baseline. In a multicenter study of participants attending healthcare facilities, Pinkerton et al.[85] compared the cost effectiveness of a seven-session risk-reduction program with a one-off education video; the former was found to be cost-saving for male participants and to cost $US32 688 per QALY for females.

3.3 General Population Interventions

Three articles assessed population-based condom distribution schemes. In Louisiana, USA, Bedimo et al.[86] found such a

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program to be cost-saving from a healthcare system perspective, based solely on the benefits gained by the state's African-American population. More broadly, Pinkerton et al.[87] estimated that a national condom distribution program would be cost-saving, with or without making allowance for lost productivity costs averted. In the UK, Hughes and Morris[88] found that national condom distribution was extremely worthwhile for men who have sex with men, costing £180 ($US330) per LYG, but was not cost effective for heterosexuals.

Papers by Holtgrave[89] and Holtgrave and Pinkerton[90] estimated the overall benefit of national prevention efforts and the probable benefits foregone if HIV incidence was not halved by 2005. When treatment costs were included, both papers found benefits far outweighed costs, although the form of future potential interventions was not specified. Gilson et al.[91] performed a randomized trial in 12 Tanzanian villages, setting up STD treatment facilities in half of them in order to reduce HIV transmissions both directly through better personal health and indirectly through education. The efficiency of the program was estimated at approximately $US10 per DALY saved. Rahman et al.[92] studied a national partner notification program in Japan, estimating it at $US4930 per LYG, although this figure was extremely sensitive to willingness to identify sexual partners.

3.4 Vaccine-Based Interventions

Two papers modeled the potential benefit of adding an HIV vaccine to WHO's Expanded Program of Immunization. In the first paper, which focused on Abidjan, Côte D'Ivoire, Cowley[93] found that a vaccine would be cost-saving from a societal viewpoint under a wide range of efficacy and seroprevalence assumptions. The later study of Bos and Postma,[94] which looked at sub-Saharan Africa more generally, estimated a program cost of just $US3.40 per DALY saved. Walensky et al.[95] modeled the therapeutic use of a vaccine for patients who had failed all available ART lines in the US. They found cost-effectiveness ratios ranging from $US19 200 to $US89 000 per QALY, depending on the assumed effectiveness of the vaccine.

3.5 Studies of Multiple Prevention Interventions

Three papers compared the efficiency of a range of prevention interventions. Kahn and Sanstad[96] found both needle exchange programs and risk behavior education for gay community leaders to be extremely cost effective, while screening surgeons for HIV infection was advisable. Over and Piot[97] estimated that well focused condom distribution and blood screening programs in the setting of a developing country would have cost-effectiveness ratios of $US0.13 and $US0.15 per DALY, respectively. They also estimated that the case management of OIs, without the use of ART, would cost $US235–384 per DALY saved. Hutton et al.[98] compared a broad range of prevention efforts in Chad. The most efficient interventions were peer-group education for sex workers and safer blood transfusion services, which cost less than $US100 per case averted. An additional group of interventions – peer-group education for youth and high-risk men, and social marketing of condoms – was estimated to cost around $US500 per case averted. Other programs, including targeted and mass prevention programs for pregnant women and voluntary HIV testing, had cost-effectiveness ratios ranging from $US1000 to $US5000 per case averted.

4. HIV Testing and Blood Screening

A total of 46 articles dealt with the cost effectiveness of testing individuals for HIV or screening blood or blood products (see table II suppl.).[99-144]

4.1 Testing Pregnant Women

Three articles considered the effect of VCT on pregnant mothers at a time when ART was not available. Brandeau et al.[99] found that the positive impact of testing in California, USA, was mainly due to changes in risk behavior induced in the mother, which included reductions in sexual partners and needle-sharing activities, leading to the program being potentially cost saving. Houshyar[100] found that the seroprevalence of the population tested in New York, USA, was crucial, and that at a 1% HIV seroprevalence rate the program cost $US795 per infection detected. In France, Le Gales et al.[101] found that a universal screening program might be cost effective compared with no program, but compared with a risk-factor based selective program it had an ICER of approximately FF400 000 ($US75 756) per infection detected.

4.2 Testing Patients and Staff in Hospitals

A review of a cohort study in St Paul, Minnesota, USA, by Henry and Campbell[102] found that with HIV testing, but not counseling, all inpatients in the hospital amounted to $US12 700 per infection detected. Lurie et al.[103] modeled the impact of such a program for the whole of the US and found that while testing had a cost-effectiveness ratio of $US16 104 per infection detected, the additional benefits for healthcare workers of such a program were very slim. Owens et al.[104] conducted a study that included both patient and partner benefits of VCT in the US and found it to cost $US55 500 per QALY saved. A study by La Croix and Russo,[105] which included benefits to patients, partners, and healthcare workers, found a cost-benefit ratio of 1 : 239 in favor of VCT. Wilkinson et al.[106] looked at which type of test to use in Hlabisa, South Africa. They found that the use of one, or even two, rapid HIV tests cost less per post-test counseled individual than using the

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traditional enzyme-linked immunosorbent assay (ELISA), due to the far higher follow-up rate in this arm.

Mullins and Harrison[107] studied a cohort of trauma patients in Wichita, Kansas, USA, but found that universal testing was not cost effective, due to the low seroprevalence among those using hospital services. Mathoulin-Pelissier et al.[108] modeled the effect of pre- or post-transfusion testing for transfusion recipients. They found pre-transfusion testing to cost $US1237 per infection detected, while adding post-transfusion testing raised this by a factor of seven. The use of a minimum benefit cut-off meant that some cheaper screening options were excluded from the final analysis.

Wallace and Carlin[109] considered testing newly diagnosed cervical cancer patients in London, UK, since HIV infection increases the risk of getting cervical cancer. The authors reported that if all patients were unaware of their serostatus this would cost more than £30 000 ($US54 955) per HIV infection detected. Finally Mrus et al.[110] looked at the incremental benefit of testing by adding a fourth ELISA or a western blot to a 3-ELISA regimen for testing infants born to seropositive mothers. Given the large proportion of true positives uncovered by the first three tests, the additional strategy had an ICER of $US500 000 or more per infection detected.

Chavey et al.[111] considered annual HIV testing for all healthcare workers, as opposed to the use of universal precautions, and found the ICER to be in excess of $US9 million per case averted. Owens et al.[112] estimated that one-off testing of surgeons would cost almost $US1.5 million per QALY saved and Sell et al.[113] reported similar results except in the case of dentists, where the estimate was around $US139 000 per case averted. When Phillips et al.[114] included the impact of changing physician practice in the light of test results, cost-effectiveness ratios remained above $US250 000 per case averted.

4.3 HIV Testing at Clinics

Varghese et al.[115] estimated that VCT in US clinics from a provider's perspective cost $US31 943 per case averted, and that adding a partner notification arm had an ICER of $US28 025 per case averted, but was cost-saving from a societal perspective. Bos et al. conducted two studies of implementing routine HIV screening in STD clinics in Holland, first in Amsterdam[116] and then in Rotterdam.[117] In both cities the program cost less than €3000 ($US3727) per LYG, although the results were particularly sensitive to changes in sexual behavior by seropositive clients. Farnham et al.[118] considered the benefit of VCT at STD, family planning, and prenatal clinics. They reported that rapid testing reduced the cost per individual who were correctly informed of their serostatus, but only when results were provided prior to confirmatory tests.

Holtgrave et al.[119] considered the impact of all counseling, testing, referral, and partner notification (CTRPN) centers nationwide across the US. They found that the cost-to-benefit ratio was more than 1 : 20 but, as observed elsewhere,[105] the results were very sensitive to a rise in risky behavior among those who tested negative. Phillips and Fernyak[120] conducted a two-stage analysis of an expanded VCT program and found that the program had a direct cost of $US4200 per infection detected. These investigators also estimated that the additional benefit from getting patients onto triple-drug ART sooner rather than later was $US23 300 per QALY saved.[120] Finally, Sweat et al.[121] used a randomized trial of VCT versus a video-based education intervention conducted among HIV clinic attendees in Nairobi, Kenya, and Dar-es-Salaam, Tanzania. The authors found that the programs in Nairobi cost approximately $US13 per DALY and in Dar-es-Salaam cost approximately $US18 per DALY, without including treatment costs. They also found that targeting the program, or getting couples to enroll together, improved these ratios.

4.4 Other Testing Interventions

The impact of pre-employment HIV testing in the US was investigated by Bloom and Glied,[122] who found that for a large firm in a city with a relatively high seroprevalence rate such an approach might be cost-saving. Zowall et al.[123] compared the cost to the Canadian public sector of testing immigrants for HIV prior to their arrival with the cost of treating infected migrants once in Canada. They found that the costs averted through pre-testing outweighed those incurred by between 1.5 and 5 times, although the study did not include any potential benefits these immigrants might bring to Canada.

Gorsky et al.[124] studied a cohort of recovering injected drug users and estimated that a VCT program would cost $US341 per client per infected person detected; it would be cost-saving if one person in 260 avoided becoming infected through associated behavior changes. Varghese and Peterman[125] modeled the effect of VCT on US prisoners who were due for release. The authors observed that at $US33 953 per averted infection this would be cost effective from a prison-system's perspective, and would be cost saving once treatment costs were factored in. Blaxhult et al.[126] evaluated the Swedish national VCT program of the 1980s. They observed that specific programs such as blood donor screening and prenatal testing had high cost-effectiveness ratios at $US1.2 million and $US96 000 per infection detected, respectively, while testing outside national programs and STD clinic screening had much lower ratios, at $US26 000 and $US18 000 per infection detected, respectively.

4.5 Blood Screening in High-Income Countries

Five studies assessed the economic impact of the US blood screening program when it used two ELISAs and a confirmatory western blot as standard screening procedure. Eisenstaedt and

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Getzen[127] found this process to be cost-saving from a societal perspective, while Schwartz et al.[128] found a cost-effectiveness ratio of between $US16 850 and $US32 275 per infection detected, depending on the seroprevalence of donors. A secondary analysis in this latter study estimated that using additional tests would cost at least $US250 000 per additional case averted. Gelles[129] estimated a program cost of between $US36 300 and $US128 833 per HIV case averted, but that the cost per AIDS case averted was at least twice the cost of these estimates. Adding an HIV-antigen test increased the cost to more than $US12 million per case averted.

AuBuchon et al.[130] estimated that the existing screening program in the US cost $US3600 per QALY, but that adding a plasma p24 or an RNA polymerase chain reaction (PCR) test would cost more than $US2 million per additional QALY saved. Busch et al.[131] used hepatitis B seropositivity to predict HIV seropositivity. They estimated that this would cost just under $US1 million per additional QALY saved, compared with existing procedures.

Two further studies looked at the US blood screening program when p24 antigen testing had become standard practice. Jackson et al.[132] estimated that adding any form of nucleic acid testing (NAT) to the existing regimen would have cost approximately $US7–10 million per additional QALY, even when including benefits related to hepatitis B and C. In a very similar analysis, Marshall et al.[133] estimated the cost for replacing p24 antigen testing with minipool NAT to be $US1.5 million per QALY.

In France, Sailly et al.[134] estimated that a policy of using an ELISA and two confirmatory ELISAs would cost FF676 596 ($US128 140) per case averted. Djossou et al.[135] focused on the incremental benefits of improving on this strategy, but none had an incremental cost below FF278 million ($US52.5 million) per additional false-negative test avoided.

4.6 Blood Screening in Sub-Saharan Africa

Watson-Williams and Kataah[136] estimated that the reintroduction of blood screening in Uganda in 1988 cost ECU21.5 ($US27) per HIV negative unit produced. Laleman et al.[137] estimated that the cost effectiveness of rapid testing from a program perspective in Shaba, Zaire, might be as low as ECU137 ($US170) per case averted. Foster and Buvé[138] found screening to be highly cost effective at $US1.32 per LYG in Monze, Zambia, even given that many clients were already seropositive. Benefits outweighed costs by a factor of 3 : 1, after taking treatment costs into consideration. This result was confirmed by Jacobs and Mercer[139] in Mwanza, Tanzania, whose program cost-effectiveness ratio was $US2.7–2.8 per LYG, and healthcare system cost-benefit ratio was 1 : 3.1–6.6. Wright and Stringer[140] compared a number of testing algorithms and found two serial tests to cost $US252 per additional incorrect result averted, compared with a single test, in a setting with 50% seroprevalence.

Finally, McFarland et al.[141] considered a program to defer or test donors with high risk factors for HIV in a factory in Harare, Zimbabwe. Deferral, particularly if based on the presence of genital ulcers or STDs, including the cost of replacing deferred donors' donations, cost as little as $US33 per case averted, while testing cost $US100 per case averted.

4.7 Other Blood-Related Interventions

AuBuchon and Birkmeyer[142] and Pereira[143] both used observational studies data to model the effect of treating blood plasma in an industrialized setting. Considering solvent-detergent treatment and virus-inactivation, respectively, both articles found that such processes were not cost effective, with costs per QALY ranging from approximately $US300 000 to $US700 000. Etchason et al.[144] considered the benefits of preoperative autologous blood donation, but in no case was this cheaper than $US235 000 per QALY, with much of the benefit arising from avoiding hepatitis C treatment costs, rather those for HIV.

5. Prevention of Mother-to-Child Transmission (MTCT)

Thirty-five articles that dealt with the cost effectiveness of preventing MTCT using ART or other interventions (see table III suppl.) were identified.[11,60,142-177] These studies used data from a number of trials to calculate their results.[177-184]

5.1 Anti-Retroviral Therapy (ART) Prophylaxis in High-Income Countries

Six studies conducted within the industrialized world – those by Gorsky et al.,[145] Grobman and Garcia,[146] Mauskopf et al.,[147] Lewis et al.,[148] Patrick et al.,[149] and Postma et al.[150] – found that the use of zidovudine was cost-saving when the cost of treating seropositive infants was included. Ecker[151] found a cost of approximately $US200 000 per case averted at the 1993 US national seroprevalence rate of 0.15% of the population, but that if the rate increased to 0.9% then routine VCT followed by zidovudine treatment was cost-saving. Dunn et al.[152] did not consider treatment costs in their study, but their cost-effectiveness ratio of £35 000 ($US64 115) per case averted was less than the lifetime treatment cost of a seropositive infant in the UK.[150] A study by Bramley et al.[11] considered the economic impact of providing dual therapy and cesarean section to all seropositive mothers in New Zealand. While the results, as in other studies, were sensitive to seroprevalence rates, the authors found the program to cost $US7336 per LYG.

5.2 ART Prophylaxis in Sub-Saharan African Countries

Six of the seven MTCT studies in African settings focused on shortened ART regimens. The paper by Mansergh et al.[153] con-

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cluded that zidovudine provision cost $US3148 per case averted from a healthcare perspective in an unspecified sub-Saharan setting. A subsequent communication[154] updated earlier findings and reported a lower cost-effectiveness ratio, and that the intervention was cost-saving from a societal perspective. Marseille et al.[155] compared a range of long- and short-course ART combinations and found that the most efficient approach was targeted single-dose nevirapine for mother and child, with a cost-effectiveness ratio of $US5.25 per DALY before infant treatment costs were considered. Sweat et al.[156] modeled the implementation of national programs for single-dose nevirapine provision in eight sub-Saharan countries. The average cost per DALY gained was $US84.

Four other studies considered MTCT in South Africa. Wilkinson et al.[157] compared the provision of full-course zidovudine with zidovudine plus lamivudine and found dual therapy to be more cost effective at $US88 per LYG, without taking averted treatment costs into account. A subsequent analysis by the same authors[158] estimated that a short-course program would cost ZAR213 ($US33) per DALY saved. Skordis and Nattrass[159] conducted a study of short-course regimens, allowing for non-ART treatment costs, and found single-dose nevirapine provision to cost just $US9.5 per DALY. Finally Wood et al.[60] estimated the cost of providing an unspecified prophylactic regimen to cover 25–75% of the seropositive pregnant women in South Africa to cost $US19 per LYG. This increased to $US133 per LYG when extended to the whole population.

5.3 Different ART Prophylaxis Regimens

In South Africa, Söderlund et al.[160] reported that treatment with *intra partum* and *post partum* zidovudine to be both more expensive and less effective than treatment provided from the 36th week of pregnancy until birth. The incremental efficiency of switching to a full-length program was over $US4000 per additional LYG. In the context of sub-Saharan Africa, Marseille et al.[161] modeled the progressive addition of *post partum* and *pre partum* prophylaxis to an *intra partum* regimen, estimating incremental costs of $US226 and $US1263 per DALY, respectively. Pinkerton et al.[162] transferred results from the Centers for Disease Control (CDC)-Thailand short-course trial[178] to a US setting to compare it with the long-course zidovudine schedule of AIDS Clinical Trial Group (ACTG) 076.[179] The authors estimated that the full-course regimen cost a further $US21 337 per additional case averted.

5.4 Other Aspects of MTCT

Three studies considered mandatory screening versus voluntary testing of mothers or infants. In the US, Myers et al.[163] found that the additional cost of introducing mandatory compared with voluntary testing was almost $US30 000 per case averted, while Immergluck et al.[164] estimated that mandatory testing was cost-saving in Chicago, Illinois, USA. The rate of adherence to prophylaxis by test recipients not captured through the voluntary programs was a crucial determinant in these studies. Zaric et al.[165] studied the impact of enhanced voluntary maternal testing and routine newborn testing and found that implementing the practices jointly would have an additional cost of less than $US11 000 per LYG.

Chen et al.[166] and Mrus et al.[167] considered adding ECS to a prophylactic regimen in the US; both studies found the procedure to be cost saving. Schackman et al.[168] modeled the use of ECS to prevent hepatitis C transmission from seropositive mothers to their offspring, and found it to cost $US6100 per QALY without considering the costs associated with HIV transmission. Halpern et al.[169] considered adding the procedure to other preventative strategies for MTCT. Adding elective cesarean sections to no ART appeared to be cost-saving, while adding it to zidovudine or combination prophylaxis had an additional cost of less than $US2000 per LYG.

Stringer and Rouse[170] studied whether to provide universal prophylaxis to all mothers or targeted prophylaxis to mothers in the US who had not received antenatal care. Selective treatment was estimated to be cost-saving relative to no intervention, but that a shift to universal treatment would cost almost $US350 000 per case averted. Mrus and Tsevat[171] considered prophylaxis following rapid testing in the same population and found both zidovudine and nevirapine provision to be cost-saving. In Africa, Stringer et al.[172] found targeted provision of nevirapine to cost $US81 per case averted, increasing to $US691 per case averted with universal provision. Rely et al.[176] considered various VCT and subsequent treatment options, such as long-course zidovudine or short-course nevirapine for prevention of MTCT, in Mexico. They found that the cost of zidovudine following targeted VCT, based on a risk questionnaire, was $US39 220 per infection averted, and rapid testing of mothers arriving without antenatal care to be even more cost effective.

Ratcliffe et al.[174] estimated the sequential benefits of adding various preventative strategies for MTCT to the UK healthcare system. Adding formula feeding to no treatment cost £15 ($US27) per case averted, adding zidovudine to the regimen with formula feeding cost £7658 ($US14 028) per additional case averted, and adding elective cesarean section as well as zidovudine to formula feeding cost £27 836 ($US50 991) per additional case averted. Two papers considered repeat maternal testing and partner testing for those women who initially tested negative. In the UK, Postma et al.[175] found that partner testing was always cost-saving, while repeat testing provided benefits at a cost of £1700 ($US3114) per LYG if used selectively, and £4400 ($US7328) per LYG if universally applied. In a US setting, Sansom et al.[173] estimated that

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repeat testing would cost $US45 708 per LYG nationally, but was cost-saving among high-risk populations. Payne and Lamb[185] modeled the use of fresh rather than frozen semen for donor insemination in the US, and found it to be cost-saving, even when reasonable medico-legal costs were factored in.

6. ART

A total of 45 articles dealt with the cost effectiveness of ART (see table IV suppl.).[60,186-229]

6.1 Zidovudine Monotherapy

Three articles considered the cost effectiveness of zidovudine compared with no ART. Two of these articles focused on a small sample of individuals; (i) Moore et al.[186] assessed a non-matched cohort and estimated a cost of approximately $US34 000; (ii) Messori et al.[187] conducted a clinical trial and estimated a cost of approximately $US37 000 per LYG. The third article by McCarthy et al.[188] looked at providing zidovudine to newly discovered asymptomatic patients following a national VCT program. It estimated the cost of the program to be less than $US10 000 per LYG in high-risk populations (such as intravenous drug users and men who have sex with men), but to cost approximately $US1 million or more per LYG among lower risk groups.

6.2 Dual Therapy

Six papers considered the cost effectiveness of adding either lamivudine or zalcitabine to zidovudine. In three papers, Lacey et al.[189-191] used outcomes from the CAESAR (Canada, Australia, Europe, South Africa) trial, alongside cost data from individual countries. Using 'disease progressions avoided' as an outcome measure, they found that over a 1-year period adding lamivudine was cost-saving in the US, and cost less than $US20 000 per disease progression averted in Canada, Germany, and the UK. The short period of follow-up used in these studies excludes the impact of late-stage disease costs deferred through dual therapy.

Simpson et al.[192] developed a Markov model, based on broader outcomes data, in which zalcitabine was added to zidovudine. The authors reported that across five European countries the cost-effectiveness ratio was relatively stable at between €12 000 ($US14 908) and €21 000 ($US26 089) per LYG. Chancellor et al.[193] modeled the same combination in the UK, finding a cost-effectiveness ratio of £6276 ($US11 497) per LYG. Davies et al.[194] combined Chancellor and colleagues' outcome model with observed costs at Addenbrooke's Hospital in Cambridge, UK, to find a cost of between £5510 ($US10 093) and £12 130 ($US22 220) per LYG. Finally, Mauskopf et al.[195] estimated the cost of adding lamivudine to zidovudine by modeling clinical trial data. Estimated costs varied from $US13 821 to $US27 045 per QALY, depending on the CD4 count at which treatment was commenced.

6.3 Triple Therapy

Six studies assessed the costs for patients receiving triple therapy, or highly active ART (HAART), compared with those not receiving ART. A US study by Freedberg et al.[196] found a cost of $US23 000 per QALY, while Sendi et al.[197] estimated a ratio of SwF33 000 ($US26 554) per LYG. Two papers by Schackman et al.[198,199] observed in the US that starting HAART at a higher CD4 count cost less than $US20 000 per QALY gained, while in a third paper[200] the same authors reported that using community- or patient-based quality-of-life weightings did not significantly alter their findings. Wood et al.[60] assessed MTCT and calculated that treating a quarter of those in need of HAART in South Africa would have a cost-effectiveness ratio of $US15 000 per LYG.

A study by Moore and Bartlett[201] compared triple therapy versus zidovudine monotherapy, finding an incremental cost-effectiveness ratio of $US10 000 per LYG. Cook et al.,[202] using clinical trial data that added indinavir to a combination of lamivudine and zidovudine therapy, concluded that over a 5-year time horizon this would be cost saving, and over a 20-year period it would have an ICER of $US13 229 per LYG. In the UK, Miners et al.[203] studied the addition of an unspecified protease inhibitor to a combination of lamivudine and zidovudine and found an ICER of £17 698 ($US32 420) per QALY. Trueman et al.[204] modeled the addition of abacavir to a combination of lamivudine and zidovudine, and found this to have an ICER of £16 168 ($US29 617) per QALY when costs and benefits were discounted at similar rates.

Anis et al.[205] modeled data from British Columbia, Canada, to compare triple and dual drug therapies. They found the change in regimen to cost between $Can46 971 ($US36 089) and $Can58 806 ($US45 183) per additional LYG. Beck et al.[206] compared the cost effectiveness of ART before and after the introduction of HAART in Québec, Canada, and found HAART to cost $US14 587 per LYG at pre-AIDS, and $US12 813 per LYG with AIDS. Le Pen et al.[207] conducted a similar study in France, matching patients from each period, and found HAART to be cost-saving in terms of improved immunologic patient outcomes.

6.4 Post-Exposure Prophylaxis

Four studies focused on occupational post-exposure prophylaxis (PEP). Pinkerton et al.[208] estimated a ratio of $US37 148 per QALY for triple therapy PEP, while Marin et al.[209] found a ratio of $US190 392 per QALY across all needlestick injuries. When only injuries involving HIV seropositive individuals were considered, the cost was estimated to be approximately $US50 000 per QALY.[209] Li and Wong[210] found an average cost per case

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averted of $US163 000 across a range of PEP therapies in the US. Finally King et al.[211] studied a small trial on the impact of using a rapid HIV assay to determine who should be given PEP. They found that the assay was cost-saving from a program perspective because it was associated with a reduction in drug costs.

Lurie et al.[212] and Pinkerton et al.[213,214] modeled non-occupational PEP; results varied depending on the nature of the exposure. Those engaging in receptive anal sex or injecting drug use were most likely to be cost effective to treat, and were frequently cost-saving to treat. Those patients who repeatedly put themselves at risk of infection were the least efficient to treat. Pinkerton et al.[215] found a non-occupational, combination therapy, PEP program for a mixed risk population in San Francisco (California, USA), to cost $US14 449 per QALY gained. A follow-up modeling exercise by the same authors[216] estimated that similar programs in 96 US cities would cost between $US4000 and $US40 000 per QALY gained.

6.5 Other ART-Related Issues

Thirteen studies covered additional ART-related topics. Wallace et al.[217] followed an open cohort of patients from 1995 to 1998, observing the fall in the death rate over time and estimating that costs rose by $US17 500 per death averted, though the precise intervention was never specified. Boulle et al.[218] modeled a number of different HAART treatment approaches in South Africa. They estimated that using generic instead of patented drugs reduced the cost-effectiveness ratio by a third to ZAR5923 ($US921) per LYG, and that adding a second line of therapy for 75% of those who failed their first line of therapy generated an ICER of ZAR8042 ($US1250) per LYG. Caro et al.[219] assessed the addition of efavirenz or indinavir to a combination of zidovudine and lamivudine, and found that efavirenz-containing regimens were both cheaper and more effective than those including indinavir. Simpson et al.[220] compared the addition of lopinavir/ritonavir or nelfinavir to lamivudine and stavudine, and found the lopinavir-containing regimen to cost $US6653 per additional QALY.

In a comparison of hospital versus home care, Tramarin et al.[221] estimated that the cost to the healthcare system associated with home care patients was less than hospital care patients, although, the study did not include the cost of informal care. McCue et al.[222] studied the use of telemedicine for managing HIV-seropositive prisoners, and observed that the program reduced the number of hospital visits made and cost less than the previous regimen. Gibb et al.[223] modeled the impact of prenatal testing in the UK in terms of the benefits to seropositive mothers from early detection and treatment with triple ART. These researchers estimated that the cost effectiveness of this early diagnosis was approximately £50 000 ($US91 592) per maternal LYG, and concluded that this was too high to promote testing of mothers.

Allen et al.[224] investigated the use of recombinant human erythropoietin compared with the use of transfused erythropoietin in the treatment of zidovudine-related anemia in seropositive children and estimated an ICER of $US1373 per transfusion averted. Goldie et al.[225] modeled hypothetical methodologies for raising adherence to ART, finding cheap interventions for late-stage disease patients to be most cost effective. Johri et al.[226] evaluated the various AIDS Drugs Assistance Programs in the US. They estimated that every increase in coverage of ART, or OI prophylaxis, had an ICER of less than $US30 000, and concluded that even the most comprehensive package was cost effective.

Weinstein et al.[227] found that the cost of genotypic resistance testing after first-line treatment failure was less than $US18 000 per QALY. Primary resistance testing was only similarly cost effective in populations with primary resistance rates of over 20%. Corzillius et al.[228] modeled resistance testing after every treatment-line failure, and found that it cost €22 510 ($US27 965) per LYG. Hughes et al.[229] investigated genotyping to detect HLA B*5701 in order to avoid abacavir hypersensitivity reactions. They found testing to be a cost-saving strategy when abacavir was replaced with efavirenz or nevirapine.

7. Prophylaxis and Treatment for Opportunistic Infections (OIs)

A total of 28 articles were identified which dealt with either the prevention or treatment of HIV-related opportunistic infections (see table V suppl.).[230-257]

7.1 Treatment of OIs

Freedberg et al.[230] considered a range of approaches for treating *Pneumocystis carinii* pneumonia (PCP). The most cost-effective strategy among high-risk patients was to obtain a diagnosis through induced sputum analysis before beginning treatment. The most cost-effective strategy for medium-risk patients was to assess the severity of the pneumonia by arterial blood gas analysis before beginning treatment. Bennett et al.[231] compared trimetrexate and pentamidine as second-line PCP treatments, and under stringent assumptions found trimetrexate at worst to cost $US10 per additional percentage point rise in toxicity-free survival over a 2-week period. Wachter et al.[232] estimated that admitting patients with PCP to the ICU cost $US174 781 per LYG, based on an historical cohort covering the 1980s. Bennett et al.[233] compared liposomal doxorubicin with daunorubicin as treatment for Kaposi's sarcoma, and reported that the former cost $US1308 per additional patient responding to treatment compared with the latter. Finally, Rachlis[234] compared intravenous ganciclovir with oral ganciclovir for the treatment of cytomegalovirus (CMV), obtaining a cost-effectiveness ratio of $US482 per progression-free day, which corresponded to $US176 000 per progression-free year.

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7.2 *Pneumocystis carinii* Pneumonia Prophylaxis

Castellano and Nettleman[235] and Freedberg et al.[236] found that trimethoprim-sulfamethoxazole (cotrimoxazole) was cost effective compared with no prophylaxis, but that adding pentamidine was probably not. A third article, by Freedberg et al.,[237] found that trimethoprim-sulfamethoxazole was both more expensive and less effective than treatment with dapsone, but that this result was extremely sensitive to relative drug efficacy and toxicity levels. The authors concluded that either drug might be cost effective. Pentamidine had a very high ICER compared with dapsone. A fourth paper by Goldie et al.[238] modeled the impact of removing HAART patients from trimethoprim-sulfamethoxazole prophylaxis once their CD4 counts had risen sufficiently. The study suggested that stopping therapy at a count of 300 cells/mm^3 had an ICER of less than $US10 000 per QALY compared with stopping at 200 cells/mm^3. A secondary analysis in the same paper reported that the most cost-effective second-line PCP prophylaxis combination was dapsone, followed by pentamidine, and then atovaqone.

7.3 *Mycobacterium avium* Complex Prophylaxis

Bayoumi and Redelmeier,[239] Freedberg et al.,[240] Moore and Chaisson,[241] and Hoffman and Brunner[242] compared various prophylaxis regimens for *Mycobacterium avium* complex. The consensus was that azithromycin was the most cost-effective medication, followed by clarithromycin, and then rifabutin. Regimens including azithromycin and rifabutin were more effective, but at a considerable additional cost. Bayoumi and Redelmeier[239] found an ICER of nearly $US100 000 per extra QALY for adding azithromycin to a rifabutin regimen. Sendi et al.[243] modeled the benefits of azithromycin for AIDS and non-AIDS patients. The cost-effectiveness benefits for AIDS patients were considerable at SwF118 ($US95) per LYG, but those for non-AIDS patients were not as favorable at SwF60 000 ($US48 280) per LYG. Scharfstein et al.[244] studied the optimal timing of starting azithromycin and concluded that beginning at a CD4 count of 50 cells/mm^3 is the most cost-effective policy, with an ICER of less than $US30 000 per QALY.

7.4 Cytomegalovirus Prophylaxis

Moore and Chaisson,[245] Paltiel and Freedberg,[246] and Paltiel et al.[247] compared oral ganciclovir with no treatment for CMV prophylaxis, and found cost-effectiveness ratios of between $US76 676 and $US173 000 per QALY. Paltiel et al.[248] and Rose et al.[249] compared the cost effectiveness of providing oral ganciclovir for all patients with providing it only to those with positive PCR tests for CMV disease. The studies found divergent cost-effectiveness results for the selective treatment; Paltiel et al.[248] reported $US59 000 per QALY and Rose et al.[249] reported $US495 158 per LYG, suggesting that even selective treatment may not be cost effective.

7.5 Other OI Prophylaxi

Scharfstein et al.[250] found that fluconazole prophylaxis was not cost effective for preventing fungal infections, costing $US96 000 per LYG even in endemic settings. Goldie et al. considered a range of screening strategies for cervical cancer in women[251] and anal squamous intraepithelial lesions in men.[252] The most cost-effective strategies were annual Papanicolau (Pap) screening for men and 6-monthly Pap smears for women, shifting to annual smears if the first two were negative. Finally, Marra et al.[253] considered the administration of pneumococcal pneumonia vaccine and estimated that providing the vaccine directly through clinics was cost-saving, compared with no vaccine assistance or only prescribing it for clients. However, it should be borne in mind, that there is no conclusive clinical evidence for the benefit of this vaccine in general populations.[258]

Two papers considered tuberculosis prophylaxis for HIV-positive individuals: (i) Rose[254] in the US; and (ii) Bell et al.[255] in Uganda. In the US, six of the seven treatment options described were cost-saving if solely analyzed in terms of direct tuberculosis-related costs, in particular daily isoniazid for 6 months. In Uganda, the various programs were cost-saving only when lost productivity, patient costs and secondary case treatment costs were factored in, but the most cost-effective regimen from a healthcare system perspective was daily isoniazid for 6 months at $US114 per QALY.

Freedberg et al.[256] and Yazdanpanah et al.[257] modeled the impact of combinations of OI prophylaxis, and estimated that trimethoprim-sulfamethoxazole for PCP and toxoplasmosis, as well as azithromycin for *Mycobacterium avium* complex, could be jointly provided at costs of less than $US30 000 per additional QALY saved. Adding fluconazole for fungal infections had, in both cases, an ICER of approximately $US60 000 per QALY, and adding ganciclovir for CMV increased the cost per additional QALY gained to well over $US100 000.

8. Mean Scores for the Studies in the Five Categories

As stated in section 2, based on the criteria in table I, all studies were independently scored to assess their methodologic strength and to reduce intra- and inter-observer variability. These scores are reported in terms of the five study categories. Three categories of study had similar mean scores: (i) the HIV prevention studies (section 3) had a mean score of 25.2 (median 24; range 15–37); (ii) the ART studies (section 6) had a mean of 25.3 (median 26; range 11–32); and (iii) the prophylaxis and treatment of OI studies (section 7) had a mean score of 24.1 (median 24; range 19–31).

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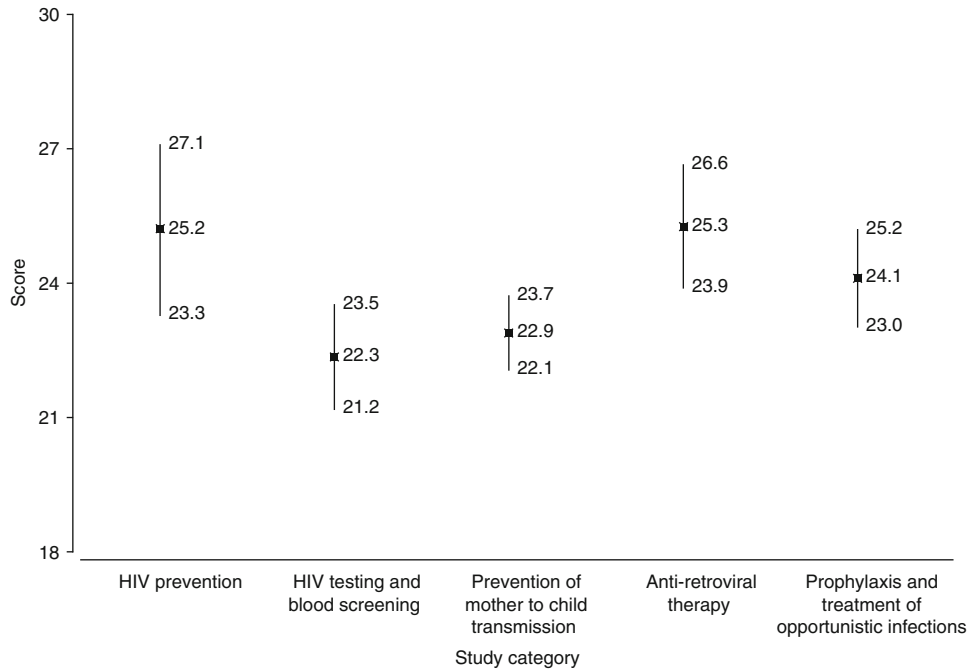

Fig. 1. Mean score and 95% confidence interval for the studies of interventions in HIV infection from 1994 to 2004, based on five study categories. Studies were assessed by criteria to ensure consistency across the reviews and to also provide a guide in evaluating the methodologic strength of the studies, particularly in terms of collection and manipulation of cost and outcomes data. Each study could potentially score a maximum of 41 points. A score of 0 for a given question indicated either that the article did not consider the matter or that insufficient information was provided to allow a judgment to be reached.

The mean for the prevention of MTCT studies (section 5) was 22.9 (median 23; range 19–28), which was significantly less than those for the prevention ($t = -2.24$, $p < 0.03$) and ART ($t = 3.00$, $p = 0.004$) studies. Similarly, the mean for the HIV testing and blood screening studies (section 4) was 22.3 (median 22; range 14–34), which was significantly less than those for the prevention ($t = -2.57$, $p = 0.01$), ART ($t = 3.27$, $p = 0.002$) and OI ($t = 2.07$, $p < 0.05$) studies (figure 1).

9. Discussion

This review had three objectives: (i) provide healthcare professionals with a review of the cost-effectiveness literature published between 1994 and 2004; (ii) highlight areas of work that urgently need to be performed, given the state of the HIV pandemic and contemporary containment programs; and (iii) highlight some of the methodologic issues raised by the studies performed to date and provide some recommendations for future studies.

Prevention of infection among adults through community interventions in high-risk, vulnerable groups appeared to be cost effective at a program level both in high income and sub-Saharan African countries; when lifetime treatment costs have been included it is often cost-saving. Possible exceptions to these results were observed among mentally ill adults and adolescents who were not yet sexually active. The level of risk behavior of the population under consideration influences the cost-effectiveness ratio, and studies considering general populations reported contradictory results.[86-88]

Testing healthcare workers routinely or cervical cancer patients after diagnosis did not appear to be cost effective, while screening clinic attendees, particularly those attending STD clinics, appears to be cost effective in both high- and low-income countries. Blood screening was reported to be reasonably cost effective in high income nations when carried out with an initial ELISA and two confirmatory tests, but additional tests or blood plasma treatment seemed to provide little extra benefit. Basic measures to improve blood services and initiate screening in sub-Saharan Africa were definitely cost-effective interventions, but no studies of the relative benefits of different test procedures in low income settings were found.

MTCT was found to be cost effective, if not cost saving, across a broad range of settings, especially as elective cesarean sections have become commonplace in the industrialized world, and short-course ART regimens are widely available in Africa. Longer treatment regimens in Africa and the imposition of mandatory testing in North America also appeared cost effective.

HAART was reported to be incrementally cost effective in high income countries, at least up to triple therapy. Its use in sub-Saharan Africa is rapidly becoming more cost effective as the price of HAART falls – the annual price of one common combination has been reduced from $US4800 to $US150 since December 2000.[259,260] This price reduction greatly improved the cost effec-

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tiveness of the use of ART in middle and lower income countries. Post-exposure prophylaxis appeared to be cost effective for healthcare workers when the source of exposure was known to be seropositive, and for high risk populations such as injecting drug users and men who have sex with men.

Prophylaxis for OIs was found to be cost effective for PCP, toxoplasmosis, and *Mycobacterium avium* complex. Fluconazole for fungal infections may be worthwhile, but ganciclovir for CMV had a high ICER, even when provided selectively. The OI treatment papers suggested that certain PCP treatment strategies are cost effective, but that ICU admission was not in a pre-HAART cohort during the 1980s.

This review was limited, as only studies published in English or French were considered. However, only seven papers among the 1172 that were initially identified had been written in other languages. Furthermore, since only peer-reviewed published articles were considered, many of the studies that comprise the 'grey-literature' will have been missed by the search. This is even more likely to be the case for those studies that were conducted outside the US or Western Europe, given that as little as 2% of MEDLINE-listed journals are published outside high income nations.[261]

In considering the breadth of the literature, it is clear that some areas are very well dealt with, but others are not addressed at all. Among all the studies reviewed, only one dealt with HIV-seropositive children,[224] and few considered adolescents[75,76,82,84] or infants.[93,94] Productivity losses, for employees or employers, were also rarely considered;[76,82,93,99,112,122,127,153,197] time and transport costs, which are often important when comparing hospital and community approaches to the same intervention, received minimal coverage.[70,71,83-85,115,215,216,255] Monitoring and evaluation of interventions was not considered in the studies reviewed, despite the potential costs that may be associated with this, especially in low income settings, while empirical evidence of the cost effectiveness of interventions to improve adherence to therapy was not included in any study.

Very few studies of community-based interventions have been published to date, and those that have been published mainly focused on prevention efforts for vulnerable seronegative individuals in high income countries. This needs to be redressed, in light of the likely future treatment and care of seropositive individuals in community settings. There were two exceptions: one study of STD treatment in Tanzania[91] and one of female sex workers in eastern and southern Africa.[72] Only one community-based HIV treatment study could be identified in this literature review,[221] but unfortunately its outcome measure would not allow for easy comparison with other hospital-based treatment interventions, nor did it include informal care costs. Although it has been suggested that community-based care, such as directly observed treatment may be cost effective relative to hospital-based treatment or other forms of directly observed treatment in the treatment of tuberculosis,[262] a debate exists concerning the applicability of such techniques in treating HIV infection.[263,264] Currently, little published evidence exists on whether directly observed treatment is cost effective in the management of HIV-positive individuals.

Over 80% of studies that were reviewed in this article focused on high income countries, the majority of studies were performed within the US. All papers dealing with low or medium income nations looked at sub-Saharan Africa, with the exception of one paper that covered the world,[69] a second concerning Ukraine,[66] and a third focusing on Mexico.[173] One published study dealt with Asia,[92] although a limited number of unpublished cost-effectiveness studies have been conducted there.[265,266] No studies from Latin America could be identified. This unbalanced pattern of research has previously been described.[267]

This lack of published evidence leaves healthcare professionals and policy makers poorly equipped to decide on the mix of interventions appropriate for their particular country. The considerable differences in cost-effectiveness ratios found in high income nations, relative to those reported from middle or low income countries are disconcerting. Furthermore, few studies have been published to date on the efficiency of tuberculosis treatment and care or the cost effectiveness of ART in low income countries.

The studies reviewed often failed to reflect the complexity of real-life situations. Some prevention papers assumed that the sexual interactions of their subjects were independent of each other when modeling the likelihood of disease transmission, even when considering a school-based population.[82] The two studies of the potential efficiency of a preventative HIV vaccine did not consider how to dispense it, other than to infants – an important issue for eligible, non-infant populations when a vaccine first becomes available.[93,94] In the field of MTCT, no study published by the end of 2004 considered the impact of triple-therapy, and nuances surrounding the lost productivity of HIV seronegative orphans have not been examined.[31,36] Also, only one study had investigated the incremental benefit of second-line ART,[218] but none had been published on the efficiency of third-line or salvage therapy. Only two papers[219,220] compared the cost effectiveness of different triple-therapy combinations; however, studies covering OIs often compared different drugs.

These gaps in the literature are disconcerting, since they indicate the limited evidence currently available for policy considerations. The methodologic limitations associated with a number of the studies are also of concern, as they cast doubt on the results reported. Many of these limitations are due to a lack of original, context-specific information.[267]

Excluding the prevention literature, where the use of program cost and behavior change data was relatively common (see table II), only a third of studies used original information as their primary data source. This presented a particular problem when the

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data were applied to a setting that differed either in time or location from that in which they were gathered, raising doubt as to the robustness of the findings.

A prime example can be seen in the MTCT literature. The ACTG 076 trial,[178] which was conducted in Western Europe and North America using zidovudine prophylaxis, provided outcome data that were used by 14 different studies.[145,147-151,153,157,159-161,163,164,174] While more than half tried to adjust for differences in geographic settings, prophylaxis regimen lengths or other factors, these studies often had to make considerable assumptions to fit the data to these differing contexts.

Over an 8-year period, at least 20 studies on OIs and ART[195,198,199,201,202,219,226,227,237,238,244-252,256] used the same cost data source from 1991–2,[268] either as their primary cost and utilization source or as part of a broader literature. Of these, only one study explicitly questioned whether such data were outdated,[226] while another verified their validity through other sources.[238] Changes in clinical practice and the relative costs of medical care over time may well have significantly affected costs, as well as efficiency estimates.[21] This implies not only that few studies collected their own data, but also that the conclusions presented in these studies are heavily dependent on the soundness of the original reference study.

Over time it is hoped that more local and contemporary data will become available. As local trial data have become available the number of context-specific efficiency studies has also increased. Two studies[195,237] tested whether a literature-based model produced similar results to a model that was based on trial data; both reported that the two approaches provided similar cost-effectiveness results.

A common response to a lack of local or contemporary data is to model various scenarios using outcome and cost data from multiple, often unrelated, sources. This is often seen in studies from sub-Saharan Africa,[153,157,159-161] but other authors have applied US healthcare costs to Thai outcomes data,[162] European costs to US trial data,[192] or Canadian quality-of-life data to UK costs.[204] In many prevention studies, the number of HIV transmissions was modeled from observed changes in behavior, using standardized, literature-based rates. However, the correlation between markers of behavior change (such as self-reported reductions in sexual partners or use of shared needles) and HIV incidence may differ widely between countries and regions, depending on cultural and other factors. Failure to account for such differences may significantly affect study results.

The uncertainty introduced by such assumptions used in modeling exercises can to some extent be mitigated through the use of sensitivity analyses, providing insights into the robustness of the main findings. In this situation, most authors make conservative assumptions, assuming that if an intervention is cost effective under these conditions then it will certainly be cost effective under more realistic circumstances. However, this makes comparisons between studies more difficult, since the magnitude of the biases introduced may neither be constant nor explicit. The problem was exacerbated by the use of widely varying outcomes measures.

Even when methodology was not problematic, several studies failed to present their work with clarity. An example of this was seen in the studies of OIs; in many of these papers it was impossible to know which drugs were being used, other than the specific intervention to treat the OI under observation.[230,231,233,234,240,241,243,254] This information is important, since a study of managing CMV conducted in the era of HAART is not directly comparable with one conducted during the era of zidovudine monotherapy. Few studies provided integrated or long-term analyses, and only a very few studies analyzed the use of a combination of interventions in a single setting,[256,257] or compared a range of interventions within a consistent analytic framework.[2,20,98,218,219,226]

The criteria provided in table I were intended as a checklist to assess the methodologic strength of the literature, rather than a scoring mechanism for comparing individual studies. As such they served a similar function as those criteria recently described for costing studies.[267] They help to highlight the observation that different analytic methods can arrive at different results, usually because they draw on different data. The results of two Canadian cost-effectiveness studies of HAART during overlapping time periods[205,206] – one based on observational data, and the other was an earlier modeling exercise – showed that the model reported a 2- to 3-fold higher cost per LYG compared with the observational study (section 6.3). However, differences can also be observed within analytic methods; that is, while some modeling exercises were based on empirical data derived from observational studies or randomized controlled trials, others used assumptions, which were primarily based on estimates. The scores also highlighted the variable quality of studies performed in the different groups.

The literature on the efficiency of interventions in HIV infection can provide some clear policy implications for different types of intervention, but when more general conclusions are drawn, disagreements may arise.[3,269] A recent review comparing prevention with treatment and care interventions in sub-Saharan Africa[18] attempted to standardize outcomes *post hoc* in order to determine which type of intervention was most efficient. As different types of interventions had different outcomes, the authors converted the results from these studies into a single cost-utility analysis outcome measure.

The use of a single conversion rate for different populations in different geographic areas, however, failed to take into account the context-specificity of many of the interventions and their effects, though many of the conversions were not out of line with results reported in the general literature. Well targeted HIV prevention efforts, especially when considered in isolation from each other,

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are often cost effective if not cost saving. Treatment and care interventions, however well focused, often have higher initial costs and lower benefits, since the drugs currently being used cannot eliminate HIV infection.

Nevertheless, conclusions from such meta-analyses will only hold if the prevention efforts focus on vulnerable individuals, and if the cost of treatment and care remain constant over time and place. With the current rapid reductions in the price of ART,[260,270] such assumptions may become rapidly outdated, and broad policy statements such as "the next major increments of HIV funding in sub-Saharan Africa should be devoted mainly to prevention and to some non-HAART treatment and care"[270] seem to be based on a limited and static interpretation of the evidence.

The time- and context-dependent nature of the results of many of these studies needs to be considered. For example, a study comparing zidovudine monotherapy with no treatment may report that monotherapy is cost effective, but once dual- or triple-therapies become available, this conclusion will become outdated if the newer therapies prove more efficient. Similarly, while it may not have been cost effective to manage people with PCP in ICU during the 1980s, this changed by the early 1990s due to changes in the baseline characteristics of patients who presented with PCP,[271] and changed even more by 2004 due to improved survival on HAART.

10. Conclusion

Research into the efficiency of HIV interventions has advanced significantly over the past decade, with the increase in data from trials and observational studies. Nevertheless, large gaps remain in both the data available[267] and the studies that have been performed.

As a consequence, too many studies have relied on data taken from multiple sources, rather than being able to use context-specific and contemporary data. Many studies also provided poor descriptions of the actual interventions compared, the data sources used and assumptions that were made, while the standards by which interventions are judged to be efficient were not always transparent or consistent.

Although the literature to date is able to guide policy in certain fields and for certain geographic locations, this is not the case for all settings. The paucity of the studies coming from countries other than a few high-income nations is very disconcerting, and this will need to be addressed as part of monitoring and evaluating the scaling up of treatment, care and prevention services in those countries with the greatest burden of disease. Therefore, there is an urgent need for a more systematic and rapid approach that seeks to answer policy-relevant questions as they emerge in this fast-developing and rapidly changing field.

One way to provide contemporary strategic information on the use, cost and outcome of HIV service provision is the development of multicenter prospective monitoring systems. This would enable the provision of information to improve patient management and monitoring and evaluation of HIV interventions and HIV services at the health facility level, as well as at sub-national and national levels.[272] Such information will be crucial for scaling up HIV-related treatment, care and prevention services in middle- and low-income countries. However, despite the prevailing rhetoric on the need for evidence-based policy formulation and evaluation, the resources required to set up and maintain systems that could provide such strategic information are often lacking.[273]

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