EVALUATION OF ACCESS TO HIV/AIDS TREATMENT AND CARE IN LATVIA

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LIST OF ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
ASAP	AIDS Strategy and Action Plan
EHRN	Eurasian Harm Reduction Network
GP	General Practitioner
HIV	Human Immunodeficiency Virus
HIV LV	NGO working on HIV issues in Latvia
IDU	Injecting Drug User
NGO	Non-Governmental Organization
PEP	Post-Exposure Prophylaxis
PLHIV	People living with HIV
PMTCT	Prevention of Mother to Child Transmission
STI	Sexually Transmitted Infection
TB	Tuberculosis
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

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SUMMARY

Latvia's HIV epidemic is spreading largely through injecting drug use. Some sexual spread is occurring between injecting drug users and their sex partners. There is no evidence of a generalized sexual epidemic nor is it likely that such an epidemic will occur. Providing effective prevention, care and treatment services focused on injecting drug users and their sex partners will control the spread of HIV in Latvia.

Some benefit is being seen from Latvia's national response to HIV. The number of men infected through injecting drug use fell from a peak in 2001. However, it remains at an unacceptable level. More needs to be done. Essential services for drug users, such as the provision of sterile injecting equipment and methadone maintenance therapy, need to be expanded across the country. In addition, these services are urgently needed in Latvian prisons. The continued absence of these services in prisons means that there is a critical gap allowing HIV transmission among individuals who could have been protected.

Antiretroviral therapy is being received by just over 300 people in Latvia. Yet, it is estimated that between 700 and 1200 people currently need such treatment. At the moment, ART is only available in one centre in Riga. As a result, three quarters of those on ART are from the Riga area. Default (non-compliance) rates among those on ART are reported to be high. Although emphasis is placed on individual patient monitoring, public health monitoring is weak with limited aggregation of data from individual patient records.

More than 67 different treatment regimens have been documented. There is evidence of excessive and over-enthusiastic use of second-line and 'salvage' regimens. This has significant cost implications. Procurement systems are relatively poorly-developed. It has not been possible to maintain this unstructured provision with available financial resources and, in 2008, there were reported stockouts of antiretroviral drugs. Such issues are likely to be even more acute in 2009, as the budget available for ART is reduced from 2008. It is clear that measures need to be taken to rationalise procurement and provision of ART to ensure the optimal use of resources available for this purpose.

There are specific concerns about the access of IDUs to ART. Although the majority of those living with HIV, in Latvia, were infected through injecting drug use, less than a third of those receiving ART have a history of injecting drug use. There is evidence of significant barriers to IDUs receiving ART both in the community and, particularly, in prisons. These barriers include stigmatising attitudes of health staff and very limited access to opioid substitution therapy with methadone.

INTRODUCTION AND BACKGROUND

Latvia has recently developed a new national HIV and AIDS strategy, entitled the National Programme for Limiting HIV and AIDS in Latvia 2009 - 2013. This was reviewed, by UNAIDS co-sponsors, through the ASAP mechanism (ASAP, 2009) at the end of 2007. That review revealed relatively high costs of ART in Latvia, as well as obstacles for access to HIV treatment. In addition, UNODC has raised concerns about limited access to treatment in prison settings and for injecting drug users (IDUs). In November 2008, the Association HIV.LV and the Eurasian Harm Reduction Network (EHRN) called the Government of Latvia and the WHO Regional Office for Europe to resolve an issue identified by them, namely the systemic problem of interruption of supply of HIV medication in Latvia.

The aim of this evaluation is to give practical input to Latvia to develop HIV treatment and care in the near future, bearing in mind the difficult economic situation in the country and the limited resources available for the health sector. The evaluation needs to assess and give recommendations on three main areas:

- The structures and systems in place,
- The coverage and quality of HIV treatment schemes, including cost-effectiveness and compliance with WHO recommendations on AIDS treatment
- Pricing and procurement policies of ARV therapy.

This evaluation has been formally requested, through the WHO Country Office, by the State Commission on HIV and TB. It is supported by the Ministry of Health as an integral part of the collaboration between the Government of Latvia, the World Health Organization and the UNODC project, entitled HIV prevention and care among injecting drug users and in prison settings in Latvia, Estonia and Lithuania.

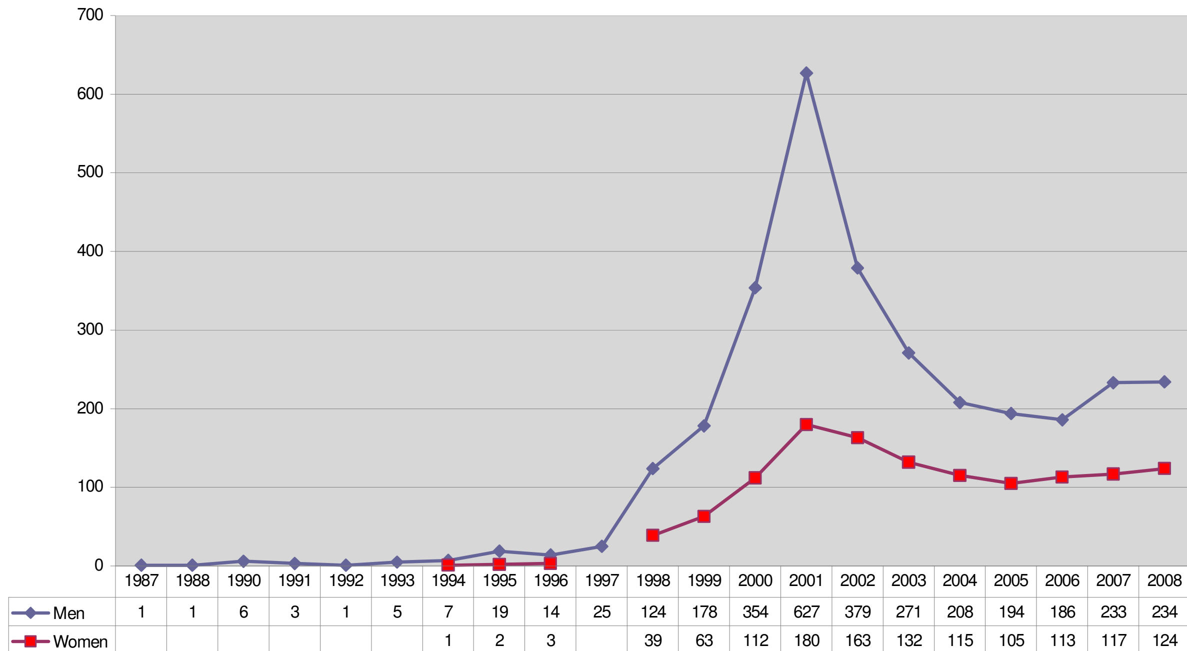
Additionally, it has been agreed that a similar, but broader, mission will take place in 2010 to evaluate the progress of the implementation of the national HIV/AIDS strategy in Latvia.

CURRENT STATUS OF THE HIV EPIDEMIC IN LATVIA

The number of new infections detected per year in Latvia peaked in 2001 (see Figure 1, overleaf). Since then, the number of new infections detected among men each year has declined, whereas the number of new infections detected among women each year has remained static. This pattern is typical of a concentrated epidemic related primarily to injecting drug use. Men become infected as a result of injecting drug use and an equal number of women are infected as a result of sex with these men (see Figure 2, p7). However, this does **<u>not</u>** signify that the epidemic is becoming generalized or that its fundamental nature is changing. Rather, it is the natural course of such an epidemic. It would

be more accurate to describe the route of transmission for these women as sex with an IDU rather than just as heterosexual transmission.

Figure 1: Distribution of newly registered HIV infections by sex



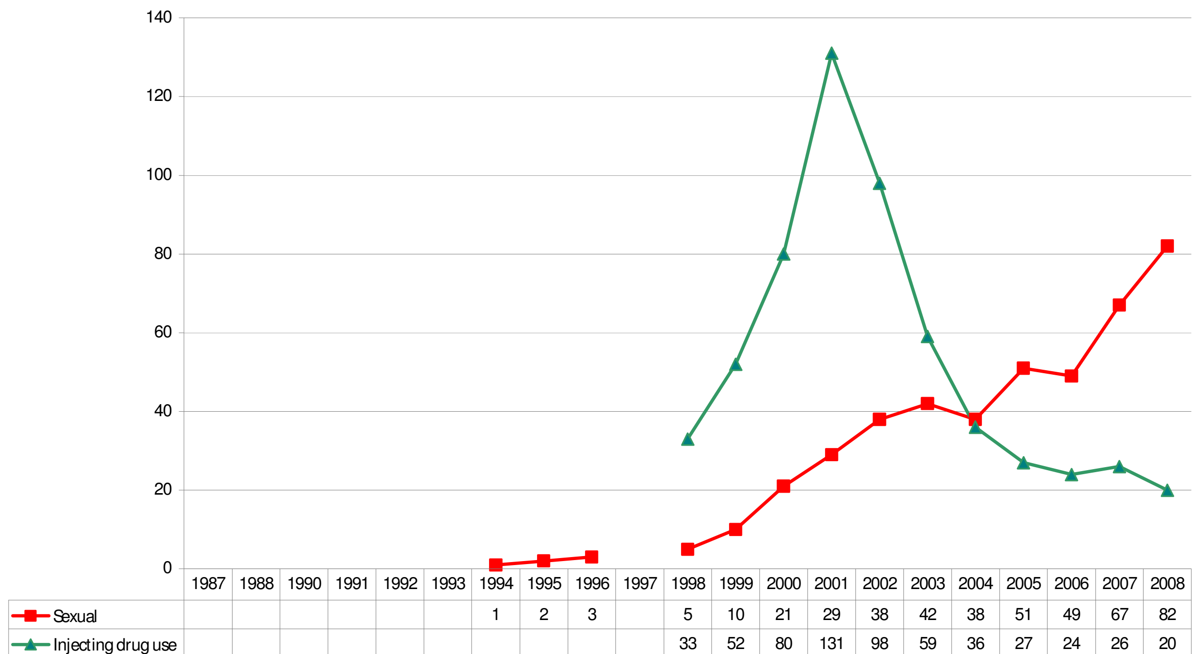
	1987	1988	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Men	1	1	6	3	1	5	7	19	14	25	124	178	354	627	379	271	208	194	186	233	234
Women							1	2	3		39	63	112	180	163	132	115	105	113	117	124

A complexity of the HIV epidemic in Latvia is that, although the epidemic is primarily affecting male IDUs and their female sex partners, there have also been a significant number of women infected through injecting drug use (see Figure 2, overleaf). As a result, some men have been infected as a result of sex with female IDUs[1] (see Figure 3, overleaf). Again, these infections would more accurately be categorised as sex with an IDU and not just as heterosexual transmission.

A truly independent, sexually-transmitted HIV epidemic would go beyond women infected by sex with male IDUs. The first sign of such an independent transmission cycle would be more and more men becoming infected with HIV without any evidence of other high risk, such as reported sex with a female IDU or infection with hepatitis C[2] or B[3]: There is currently no such evidence of generalization of the epidemic, e.g. men becoming infected, who have not injected drugs and have not had sex with a female IDU or with men.

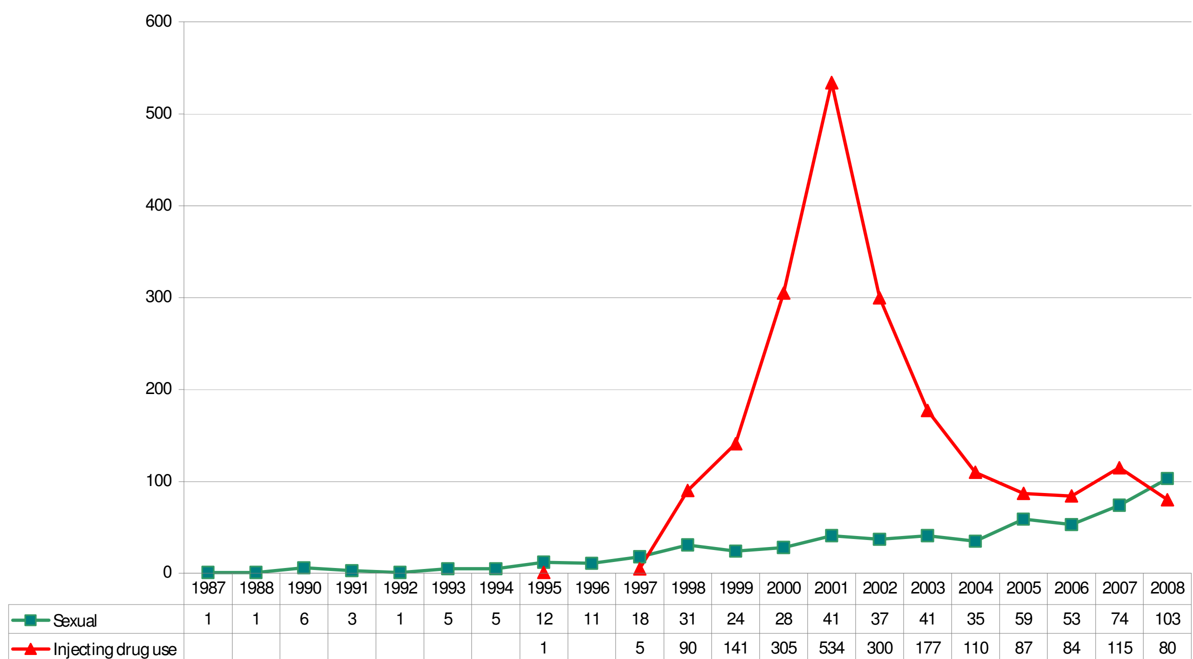
[1] In some cases, such sex is paid for
[2] A proxy marker of injecting drug use
[3] A proxy marker for men having sex with men

Figure 2: Newly- registered HIV infections by transmission route (women)



	1987	1988	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Sexual							1	2	3		5	10	21	29	38	42	38	51	49	67	82
Injecting drug use											33	52	80	131	98	59	36	27	24	26	20

Figure 3: Newly-registered HIV infections by transmission route (men)



	1987	1988	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008
Sexual	1	1	6	3	1	5	5	12	11	18	31	24	28	41	37	41	35	59	53	74	103
Injecting drug use								1		5	90	141	305	534	300	177	110	87	84	115	80

Correctly understanding these issues is of critical importance for an effective response to HIV and AIDS in Latvia. Evidence from other countries shows that HIV transmission through injecting drug use can be controlled by effective prevention measures, such as harm reduction interventions. These measures not only protect those who inject drugs but also the entire population. There is some evidence that these measures are beginning to have a positive effect in Latvia, as evidenced by the reduced number of men infected annually through injecting drug use, since the peak in 2001. However, the number of new infections per year through injecting drug use remains relatively high, indicating that these interventions need to be prioritized and delivered at an increased scale, if further progress is to be made. Such measures will also contribute to a reduction in sexual transmission of HIV, particularly if combined with elements of 'positive prevention' and partner management of HIV positive IDUs, both male and female.

It is therefore of concern that these trends are frequently misinterpreted in Latvia and other countries. They are cited as evidence of the epidemic changing to one where the main transmission route is heterosexual. As a result, there is a significant risk that the correct priorities will not be addressed and prevention interventions will not be adequately designed and targeted.

METHOD

Terms of Reference for the evaluation are provided as Annex 4 (p**Error! Bookmark not defined.**). Most of the data for this evaluation was collected during a team visit to Latvia in March 2009. A series of meetings were held with key informants, structured around different topics of the evaluation (see Annex 1, p**Error! Bookmark not defined.**). Key informants included relevant government officials in various ministries, the Public Health Agency, the Latvian Centre of Infectious Diseases, the State TB and Pulmonary Diseases Agency, the State Compulsory Health Insurance Agency, the State Medicines Pricing and Reimbursement Agency, the Riga Centre for Psychiatry and Addictions, the Prisons Administration and representatives of NGOs. A number of site visits were made, including to health institutions and prisons.

In addition, a wide range of documents were reviewed by the team (see Annex 2, p**Error! Bookmark not defined.**).

Each team member compiled an individual report on specific areas on which they were asked to concentrate. These were compiled into this overall report by Roger Drew[4].

[4] He did not accompany the team on the visit to Latvia in March having been there just prior to the visit for the evaluation of the UNODC regional project (Drew, 2009)

FINDINGS

<u>Structures, Systems and Organizational Development.</u>

Healthcare systems connected with services for PLHIV

Leadership and the strategic environment

Ideally, the delivery of health services for PLHIV should be part of an overall national response to HIV and AIDS, based on an agreed strategy and a costed action plan. All actors should then contribute to delivery of this national AIDS strategy and action plan, rather than developing stand-alone projects. However, in Latvia, there have been delays in developing and agreeing the national HIV/AIDS programme for 2009-2013. At the time of the team's visit, it had still not been formally adopted, and, in particular, the budget had not been approved. A similar situation applies to the national TB programme.

The reasons for these delays are not fully understood. However, they seem to reflect unclear responsibilities and structures for leadership on public health in Latvia. The leading ministry in Latvia's response to HIV and AIDS is the Ministry of Health. However, the ministry has been less active in leading the response to HIV and AIDS than some respondents had hoped. This may reflect limited capacity in this area, including to coordinate and monitor the activities of other ministries. Overall coordination is expected to be achieved through the State Commission on HIV and TB (National Coordination Committee for HIV and STI Prevention, 2009). However, this commission is located within the Ministry of Health[5] and has had limited success in involving other ministries, e.g. the Ministry of Education, in the national response to HIV and AIDS. Other similar bodies, e.g. the Drug Control and Drug Prevention Coordination Council are located at a higher level, i.e. the Cabinet of Ministers, and this might provide a useful model for HIV and AIDS. In addition, within the Ministry of Health, responsibilities on HIV and AIDS are divided between the public health and health care departments.

There are practical implications of the delay in finalising the national programme on HIV and AIDS. The National AIDS Centre reports having insufficient funds for prevention activities. Lines of responsibility, e.g. between central government and municipalities over who funds what are reported to be unclear.

ART provision

Currently, in Latvia, all antiretroviral therapy is provided through one tertiary level, referral facility, the Centre of Infectious Diseases, in Riga (Januskevica,

[5] It is led by the Public Health Agency, which is a government body subordinated to the Ministry of Health

undated). The centre first started providing ART in 1996 and has both inpatient and outpatient facilities for people living with HIV. It provides:

- Laboratory and clinical monitoring of patients
- HIV/AIDS treatment and care, including ART
- ARVs for prevention of mother-to-child transmission of HIV
- Post-exposure prophylaxis for medical practitioners
- Laboratory confirmation of HIV infection for the network of 24 laboratories performing screening on HIV
- An HIV/AIDS hot-line
- Training of medical professionals

The centre also participates in clinical trials in the area of HIV/AIDS treatment. TB services are not available at the centre. Rather, for assessment, diagnosis and management of TB, all people living with HIV are referred to a separate TB clinic. Diagnosis and treatment of hepatitis is available in the centre although there are cost-sharing mechanisms in place for this which limit uptake of the services and are discussed elsewhere in this report (p24). Patients with hepatitis B or C are not routinely offered HIV testing in this and other centres. Opioid substitution therapy, though available in Riga, is not provided at the centre[6]. Although such treatment has been provided since 1996, the numbers receiving treatment remain very low[7] due largely to very strict eligibility criteria[8]. It is reported that the centre has established good links with the penitentiary system and provides ARVs for those imprisoned to ensure a continuum of care. Once a month prisoners are allowed to visit the centre to receive ARVs.

The centre's out-patient unit has eight physicians[9] and five medical nurses. Other specialists are available as consultants. It is reported that, on average, the unit serves 40-50 patients per day. The in-patient unit has 18 beds[10] and two physicians who provide treatment and care.

As of 1st March 2009, a total of 4,360 people living with HIV had been registered in Latvia. Of these, around two thirds (67%) are registered with the Centre of Infectious Diseases. Around two thirds (67%) of those registered with the centre were infected with HIV through injecting drug use.

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[6] Although it is reported that those admitted to the centre are able to continue on methadone if they were receiving it at the time of their admission

[7] In 2008, it was reported that 103 people were receiving methadone and 61 buprenorphine. Since then, it appears that provision of buprenorphine has been discontinued for 53 foreign citizens.

[8] Eligibility criteria for opioid substitution therapy include five years of drug use experience, two episodes of unsuccessful treatment and one or more of the following conditions - HIV infection, tuberculosis, hepatitis C, or pregnancy.

[9] Including three infectious diseases specialists and two paediatricians.

[10] These were fully occupied at the time of the team's visit.

At the time of the visit, it was reported that 313[11] people were receiving ART in Latvia (see Table 1, overleaf). However, it is estimated by the Centre of Infectious Diseases that between 700 and 1200 people are in need of ART. Also, it is unclear how many of those currently on treatment receive their medications regularly. According to information provided by health authorities, about 40%[12] of people who start ART do not come back for continuation of treatment. An unverified report was received by the team that there are only about 100 'long-term' ARV patients, plus around 28[13] children, who receive their medication regularly and consistently. If this report proved true, it would be a cause of extreme concern.

The Centre of Infectious Diseases issued guidelines for the treatment of HIV infection in 2007. The guidelines differ significantly in approach from the clinical protocols for the WHO European Region (WHO, 2007). Most importantly, they promote a highly individualized approach for each patient without considering potential cost benefits of more standardized treatment regimens. As a result, the guidelines differ from WHO clinical protocols on regimens for first line, second line and 'salvage' use. It should be noted that throughout this document the terms first line, second line and 'salvage' regimens are used in the way defined by WHO. They are not necessarily used this way in Latvia. Indeed, one of the key issues raised in this report is that more expensive regimens reserved by WHO for second line and 'salvage' therapy appear to be being used early for first line use without adequate justification. Similarly, regimens, which are reserved by WHO for 'salvage' use, appear to be promoted for second line use. Other significant problems with the guidelines include:

- The lack of a comprehensive approach to treatment and care of PLHIV that addresses different health-related needs, including management of HIV/hepatitis co-infections, management of opportunistic infections, palliative care, reproductive health, immunization, etc.
- Lack of specific evidence-based recommendations to guide medical professionals in their day-to-day practice.
- Promotion of drug resistance testing before initiating ART despite a lack of evidence of drug-resistant strains in the country

As a result of the approach used in the guidelines, the centre currently uses more than 60 different ART treatment regimens. At the time of the team's visit:

- 225 patients were receiving a total of 19 different regimens that WHO recommends as first line regimens

[11] A variety of figures were reported to and by the team, ranging from 313 to 336

[12] The calculations of ART monitoring costs use a figure of 450 for those who received ART in 2008. Assuming 313 continuing on treatment, this would mean that 137 stopped treatment for some reason, i.e. 37% of the total.

[13] Other figures provided to the team give the number of children known to be HIV infected as 29. Of these, 23 are reported to be on treatment.

Table 1: Treatment regimens currently being used in Latvia

										Treatment category	# of Patients	Costs/pat/mo (Ls)	Costs/pat/year (Ls)	Costs/all pat/mo (Ls)	Costs/all pat/year (Ls)	% of all costs
2	EFV	+	3TC/AZT							first line	139	309	3,714	43,017	516,203	29.3%
4	EFV	+	ABC/3TC							first line	38	385	4,623	14,638	175,655	10.0%
9	EFV	+	3TC	+	d4T					first line	11	334	4,013	3,679	44,148	2.5%
1	ABC/3TC/AZT									first line	10	396	4,752	3,960	47,520	2.7%
8	EFV	+	3TC	+	ddI					first line	10	371	4,447	3,706	44,467	2.5%
5	EFV	+	3TC	+	ABC					first line	3	363	4,360	1,090	13,079	0.7%
30	SQV	+	RTV	+	3TC	+	d4T			first line	2	694	8,331	1,388	16,661	0.9%
3	EFV	+	3TC	+	AZT					first line	1	342	4,098	342	4,098	0.2%
6	EFV	+	FTC/TDF							first line	1	695	8,343	695	8,343	0.5%
7	EFV	+	FTC	+	TDF					first line	1	730	8,755	730	8,755	0.5%
10	EFV	+	ABC	+	ddI					first line	1	437	5,242	437	5,242	0.3%
11	EFV	+	ABC	+	AZT					first line	1	408	4,894	408	4,894	0.3%
12	EFV	+	ABC	+	FTC					first line	1	469	5,630	469	5,630	0.3%
13	EFV	+	AZT	+	ddI					first line	1	415	4,981	415	4,981	0.3%
14	EFV	+	FTC	+	AZT					first line	1	447	5,369	447	5,369	0.3%
15	EFV	+	FTC	+	ddI					first line	1	476	5,717	476	5,717	0.3%
24	NVP	+	3TC/AZT							first line	1	487	5,849	487	5,849	0.3%
25	NVP	+	ABC/3TC							first line	1	563	6,758	563	6,758	0.4%
26	NVP	+	FTC/TDF							first line	1	873	10,478	873	10,478	0.6%
31	LPV/RTV	+	3TC/AZT							second line	11	627	7,525	6,898	82,778	4.7%
27	SQV	+	RTV	+	3TC/AZT					second line	8	669	8,031	5,354	64,247	3.7%
61	FPV	+	RTV	+	3TC/AZT					second line	7	676	8,108	4,730	56,759	3.2%
17	IDV	+	3TC/AZT							second line	5	326	3,912	1,630	19,562	1.1%
28	SQV	+	RTV	+	ABC/3TC					second line	4	745	8,940	2,980	35,759	2.0%
35	LPV/RTV	+	ABC	+	AZT					second line	4	725	8,705	2,902	34,821	2.0%
39	ATV	+	RTV	+	3TC/AZT					second line	4	668	8,015	2,672	32,060	1.8%
41	ATV	+	RTV	+	ABC/3TC					second line	4	744	8,924	2,975	35,695	2.0%
19	IDV	+	ABC	+	AZT					second line	2	424	5,093	849	10,185	0.6%
18	IDV	+	3TC	+	AZT					second line	1	358	4,297	358	4,297	0.2%
20	IDV	+	ABC	+	TDF					second line	1	707	8,478	707	8,478	0.5%
21	IDV	+	ABC	+	ddI					second line	1	453	5,441	453	5,441	0.3%
22	IDV	+	RTV	+	3TC/AZT					second line	1	409	4,910	409	4,910	0.3%
23	IDV	+	RTV	+	3TC	+	ddI			second line	1	470	5,643	470	5,643	0.3%
29	SQV	+	RTV	+	3TC	+	ABC			second line	1	723	8,677	723	8,677	0.5%
32	LPV/RTV	+	ABC/3TC							second line	1	703	8,434	703	8,434	0.5%
33	LPV/RTV	+	3TC	+	ddI					second line	1	688	8,258	688	8,258	0.5%
34	LPV/RTV	+	3TC	+	d4T					second line	1	652	7,825	652	7,825	0.4%
36	LPV/RTV	+	EFV	+	d4T					second line	1	544	6,529	544	6,529	0.4%
37	LPV/RTV	+	SQV	+	d4T					second line	1	821	9,848	821	9,848	0.6%
38	LPV/RTV	+	FTC/TDF							second line	1	1013	12,155	1,013	12,155	0.7%
40	ATV	+	3TC/AZT							second line	1	626	7,516	626	7,516	0.4%
42	ATV	+	RTV	+	3TC	+	ddI			second line	1	729	8,748	729	8,748	0.5%
43	ATV	+	3TC	+	d4T					second line	1	651	7,816	651	7,816	0.4%
44	ATV	+	RTV	+	3TC	+	TDF			second line	1	982	11,785	982	11,785	0.7%
45	ATV	+	RTV	+	ABC	+	AZT			second line	1	766	9,195	766	9,195	0.5%
46	ATV	+	RTV	+	AZT	+	ddI			second line	1	774	9,282	774	9,282	0.5%
47	ATV	+	AZT	+	ddI					second line	1	732	8,783	732	8,783	0.5%
48	ATV	+	RTV	+	AZT	+	TDF			second line	1	1027	12,320	1,027	12,320	0.7%
49	ATV	+	RTV	+	TDF	+	d4T			second line	1	1020	12,235	1,020	12,235	0.7%
50	RTG		TPV	+	RTV	+	EFV			"salvage"	1	810	9,722	810	9,722	0.6%
51	TPV	+	RTV	+	TDF	+	AZT			"salvage"	1	1424	17,092	1,424	17,092	1.0%
52	T20	+	SQV	+	RTV	+	EFV			"salvage"	1	1617	19,402	1,617	19,402	1.1%
53	T20	+	DRV	+	RTV	+	3TC	+	ABC	"salvage"	1	2132	25,584	2,132	25,584	1.5%
54	T20	+	DRV	+	RTV	+	FTC/TDF			"salvage"	1	2464	29,568	2,464	29,568	1.7%
55	T20	+	EFV	+	ABC/3TC					"salvage"	1	1588	19,059	1,588	19,059	1.1%
56	T20	+	EFV	+	ddI					"salvage"	1	1439	17,263	1,439	17,263	1.0%
57	T20	+	FTC	+	TDF					"salvage"	1	1906	22,867	1,906	22,867	1.3%
58	T20	+	ABC	+	ddI					"salvage"	1	1613	19,355	1,613	19,355	1.1%
59	T20	+	ABC	+	d4T					"salvage"	1	1577	18,922	1,577	18,922	1.1%
60	DRV	+	RTV	+	EFV	+	AZT			"salvage"	1	799	9,590	799	9,590	0.5%
62	FPV	+	RTV	+	ABC/3TC					"salvage"	1	751	9,017	751	9,017	0.5%
63	FPV	+	RTV	+	3TC	+	d4T			"salvage"	1	701	8,408	701	8,408	0.5%
64	FPV	+	RTV	+	ABC	+	ddI			"salvage"	1	803	9,637	803	9,637	0.5%
65	FPV	+	RTV	+	ABC	+	TDF			"salvage"	1	1056	12,674	1,056	12,674	0.7%
66	FPV	+	RTV	+	FTC	+	ddI			"salvage"	1	843	10,112	843	10,112	0.6%
67	FPV	+	RTV	+	AZT	+	ddI			"salvage"	1	781	9,376	781	9,376	0.5%
16	EFV	+	ddI	+	SQV	+	RTV			X not recommended	1	622	7,468	622	7,468	0.4%
											313	468	5,620	146,584	1,759,008	100.0%
										first line	225	346	4,150	77,821	933,847	53.1%
										second line	70	655	7,858	45,837	550,044	31.3%
										"salvage"	17	1,312	15,744	22,304	267,649	15.2%
										X not recommended	1	622	7,468	622	7,468	0.4%

- 70 patients were receiving a total of 30 different regimens that WHO recommends as second line regimens
- 17 patients were receiving a total of 17 different 'salvage' regimens that WHO only recommends in cases where all other regimens have failed
- One patient was receiving a combination that is not recommended by WHO or in any other international guidelines (see Table 1, p12)

The rationale for the selection of different regimens for different patients is unclear. Information on how long patients were on each regime or what regimens they were on prior to the current regimen is not available in aggregated form. However, given that ART has been available in Latvia for a relatively short period, it seems unlikely that such relatively large numbers of patients would require second line or 'salvage' treatment because of failure to respond to first line or second line drugs. It is also unclear why so many different regimens, a total of 67 overall, are offered in Latvia across the different levels. The significant financial implications of this approach are discussed elsewhere in this report (p19).

There have been several times over the last four years when ARV treatment has been interrupted in Latvia. The most recent of these occurred between November and December 2008 and was one of the triggers for this evaluation. Such treatment interruptions are of huge concern because of the risk of promoting drug resistance which could have profound implications for both individuals and public health, more broadly. In addition, treatment interruptions make it likely that second line and 'salvage' regimens will need to be introduced earlier than would be necessary if there was a steady and reliable supply of ARVs. The explanation provided by the centre's leadership is lack of adequate financial resources, particularly given the current financial crisis. However, there appear to be other factors. For example, annual contracts for delivery of particular ARVs with one supplier mean considerable problems are encountered if that supplier fails to deliver the required ARVs within the specified time frame.

Role of NGOs

In principle, the importance of involving NGOs in an effective national response to HIV and AIDS is recognized in Latvia. However, there may not be consensus on precise roles for NGOs or the reasons why NGOs are best-placed to perform those roles. Suggested roles for NGOs include low threshold centres, needle exchange services, counselling for methadone maintenance treatment and ART adherence support. NGOs may be better able to provide these services than government because they are more trusted by service users.

Examples of treatment-focused services currently provided by NGOs include:

- Advocacy through mass media, web sites and on individual cases
- Lobbying for an increase in the ART budget

- Lobbying for introduction of latest ARVs
- Treatment literacy and a treatment advocacy group provided by Agihas
- Information sheets produced by Agihas
- A brochure in Latvian entitled 'An Introduction to Combined Antiretroviral Therapy' produced by HIV LV

Dialogs provides a range of services focused on IDUs. However, to date, these have not had a particularly strong focus on ART provision.

Mechanisms for channelling government funds to NGOs are not well-developed. As a result, funding flows to NGOs are unpredictable and this hampers their organizational development. They tend to be more focused on immediate and short-term funding needs rather than longer term issues, such as developing fundraising strategies, risk assessments and reserves policies. There is a need for a systematic programme of capacity building among NGOs to improve their professional skills, including in the areas of management and fundraising.

Institutional assessment of key actors involved in HIV treatment

The biggest capacity constraint concerning the provision of ART in Latvia is the concentration of services in a single institution in Riga, the Centre of Infectious Diseases. As a result, three quarters (75%) of those on ART live in Riga or the Riga region (see Figure 4[14], overleaf). It is reported that people living with HIV receive their ARVs weekly from the Centre of Infectious Diseases. It appears that some people can receive their treatment monthly, e.g. if the person works, travels or is ill[15] and has shown good adherence.

Management and coordination of HIV treatment in the community and in prison settings

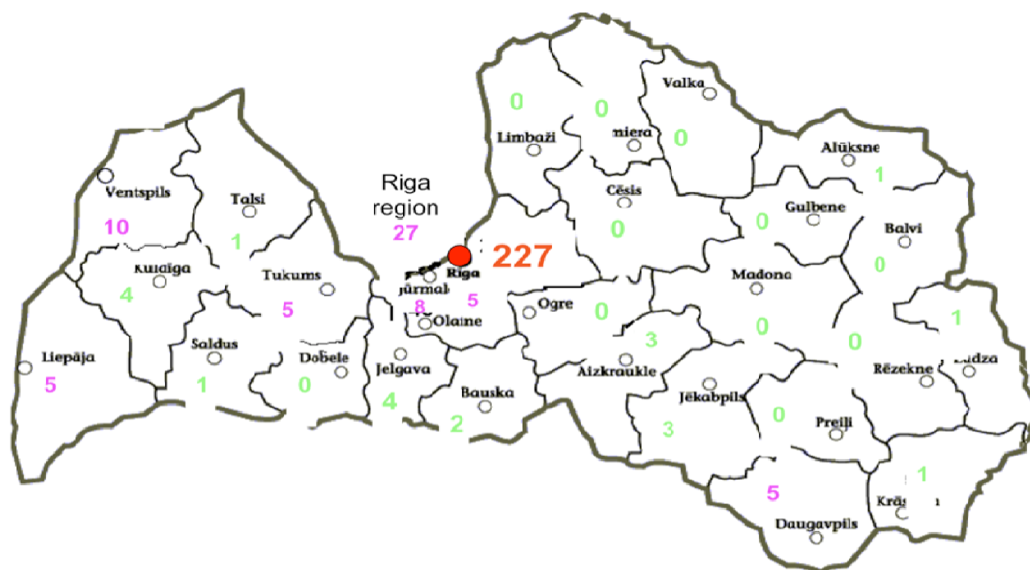
There are about 7,000 people in 12 Latvian prisons. The incarceration rate is almost 300 per 100,000 population, which is one of the highest rates in the EU (Stöver, 2007). Health services for prisoners are managed directly by the prison system, not the Ministry of Health. Reform of this system has been proposed with the Ministry of Health taking responsibility for health services in prisons. However, this proposal has not been implemented. Although it may be argued that such a move might save money overall, it would require additional spending by the Ministry of Health and would result in that ministry becoming responsible for an area known to be problematic and challenging. It is reported that money available for health in the prisons system in 2009 has been reduced from 2008 levels because of the financial crisis and that the prison system will no longer have earmarked funds for health. Rather, health spending will be financed out of

[14] Based on figures in this map, there are 340 people on ART. This figures differs slightly from that supplied to the team

[15] If someone lives outside of Riga and are ill, they would attend their GP. Under these circumstances, a family member would be permitted to collect their ARVs for a month.

overall funds available for prison services. Previously, the budget for health per prisoner was around Lats 12 per year.

Figure 4: Geographical distribution of people living with HIV receiving ART



HIV is a significant problem in Latvian prisons. HIV prevalence amongst all prisoners is 6.6%. It is reported to be 5.7% among male prisoners and 18.1% among female prisoners. Among those prisoners who are know to inject drugs, HIV prevalence is reported to be 95%. Evidence from Valmiera prison suggests that 15% of prisoners use drugs (UNODC, 2008b).

Details concerning access to ART in prisons are provided elsewhere in this report (see p23).

National funding plans and financial flow for HIV testing and treatment

Overall, government spending on health has been increasing in Latvia in recent years and accounted for 57% of total health expenditure in 2007[16]. Meanwhile, out-of-pocket health expenditure, as a share of total health expenditure, decreased to 40.9% in 2007 from 45.2% in 2002. As in many countries, the financial crisis has resulted in a downward revision of the 2009 state budget due to a lower revenue base. The health sector budget 2009 was already reduced in

[16] These figures come from WHO health expenditure estimates available on www.who.int/nha accessed on 5th May 2009

a first revision in late 2008 and it has been requested to plan for an additional reduction by around 20%.

As a result of reduced state budgets for health, it is reported that co-payments for health services, such as primary care consultations, visits to specialists, hospital fees and medicines, have increased. There is a risk that this will make it more difficult for the population, particularly low income groups, to afford health care. This issue does not apply to ARVs or TB drugs, as these are provided free with no expectation of co-payment. Also, some patient groups, including those with a mental illness, dependency on alcohol or drugs, TB or STIs are covered completely from the state budget and are exempted from co-payments. However, this exemption applies only to health services and not to pharmaceuticals (HIT, 2008). This is of particular relevance to the treatment of opportunistic infections and hepatitis.

In line with the health budget cuts, the overall funding of prevention and treatment for HIV/AIDS has been reduced. For example, the health care budget allocations to the Centre of Infectious Diseases for ARV drugs and ARV monitoring have been reduced in 2009 as compared to 2008 (see Table 2).

Table 2: Estimated budget of the Centre of Infectious Diseases for HIV/AIDS in 2008 and 2009 (Lats[17])

	2008	2009	% change
ARV drugs	2,924,291[18]	2,160,000	-26%
HIV reagents	57,990	48,000	-17%

The estimated HIV/AIDS programme budget for 2009 is around 4.2m lats (see Table 3, overleaf). Of this, more than half (57%) is allocated to ARV drugs and treatment monitoring. Just over a quarter (27%) is allocated to treatment and rehabilitation of IDUs. Consequently, other important preventative and related services are allocated a relatively low share of the total budget. Some activities receive no funding in the 2009 state programme budget, including various trainings for professionals, awareness raising activities, the development or review of different guidelines, HIV testing in prisons, funds to promote NGO involvement in the work of the HIV State Commission and the mid-term review of the national HIV/AIDS programme.

Of particular concern is the very limited funding provided by the state budget for effective prevention strategies. Providing ART is relatively expensive, costing around Lats 5,200 to 6,400 per person per year[19] (Alban and Miezitis, 2007). In comparison, effective prevention programmes are estimated to cost Lats 200-500

[17] At the time of writing 1 Lat = US$ 1.85787
[18] Includes additional Ls 208,000 allocated in November 2008 to cover ARV funding gap
[19] Based on figures from Table 1, the average cost of ART in Latvia is 5,620 Lats per person per year. Prices per individual vary greatly depending on the regimen selected.

per person per year. A costing exercise conducted in Estonia in 2005 calculated a cost of US$ 233 per year per IDU for an effective needle exchange programme and US$ 1,811 per year per IDU for a methadone treatment programme (Alban, 2005). A further report concluded that "*the alternative to these HIV preventive interventions is that more IDUs get infected through unclean needles who will have to be treated at the cost of ART per year per person that is much higher comparatively to needle exchange and oral substitution programmes*" (Alban and Kutzin, 2006).

Table 3: Estimated HIV/AIDS programme budget in 2009 (Lats)

Total estimated programme budget	**4,191,455**	**100%**
ARV therapy , including monitoring of quality and resistance, treatment of co-infections (331 patients on ARV in 2009)	2,380,508	57%
Treatment and rehabilitation of injecting drug users	1,140,303	27%
ARV and TB therapy in prisons	267,483	6%
Vertical transmission prophylaxis	92,625	2%
Voluntary HIV testing (incl. tests and primary testing/consultation of 15790 p.)	82,392	2%
Purchase of HIV tests	79,920	2%
Maintenance of AIDS hotline	49,448	1%
Improve registration of HIV/AIDS cases and analysis	23,852	3%
Establish methadone programme outside of Riga city	15,885	
Research	15,280	
Consultation cabinets (pre and post HIV test)	14,313	
Needles/syringes exchange and other prevention means, incl. condoms and disinfectants	11,780	
Post-exposure prophylaxis (estimated nr in 2009: 21 p.)	8,694	
Participation in ENCAP project	4,422	
Prevention activities outside Riga City	2,190	
T-SPOT tests	1,400	
Express tests offered to all pregnant with un-known HIV status	600	
Maintenance of web sites of Public Health agency on HIV/AIDS	360	

Source: Ministry of Health

There are, however, concerns that the HIV/AIDS programme budget may be reduced in line with any further reductions in the health care budget.

Detailed issues regarding ARV prices are considered elsewhere in this report (p19).

Organizational development of coordinating institutions and service providers

There are a number of structural and systemic issues which need to be addressed through organizational development of coordinating institutions and

service providers if ART is to be provided in a more effective way in Latvia. Key steps would include:

- Clearly defining the roles and responsibilities of different actors, e.g. state and municipal level government
- Ensuring adequate financial resources for actors to fulfil their roles and responsibilities
- Building the capacity of the Ministry of Health to lead, coordinate and monitor the national response to HIV
- Integration of the prison health care system into the general system of the Ministry of Health
- Building the capacity of the Ministry of Health to ensure a consistent supply of ARVs
- Building the authority and capacity of the State Commission on AIDS
- Developing attractive career paths for staff working on the response to AIDS, and ensuring that these allow crossover from government to NGOs and vice versa

NGOs are beginning to do some work on organizational development. For example, HIV LV has developed a strategic plan. However, such developments are at an early stage and are hindered by the uncertainty in sources of funding for the work of NGOs.

Integration of services

The organization of medical services in Latvia still, to some extent, reflects the historical development of those services when the country was part of the Soviet Union. As a result, HIV treatment, TB treatment and treatment of drug addiction are all handled by different providers. For example, a person living with HIV needs to attend the TB clinic for investigation and treatment of TB. This can not be handled at the Centre of Infectious Diseases. Similarly, methadone is provided elsewhere, not at the Centre of Infectious Diseases. Cooperation between the Centre of Infectious Diseases, TB services and drug treatment services could be stronger.

In 2006, a study was conducted which explored the benefits of more structured collaboration between the providers of TB and HIV services, specialized health care facilities[20], municipalities[21], NGOs and human right organizations in Latvia. The report highlights that financing of HIV and TB services '*remains fragmented between the two Ministry of Health programmes creating disincentives to joint planning and especially pooling of resources to increase effectiveness'*. It proposed a 'client-oriented' approach as an alternative with the objective of

[20] Including in prisons
[21] Including representatives from GPs

reaching IDUs to both reduce drug use and HIV transmission (Alban and Kutzin, 2006).

The problem of a financial and managerial separation also applies to the prison health system in relation to the general health system. This does not promote efficiency and joint achievement of public health targets.

Involvement of PLHIV

There is some involvement of PLHIV in treatment and care services through a small number of NGOs including a PLHIV support group[22], NGOs which provide support groups for PLHIV[23] and an NGO that provides services for IDUs[24]. Activities of these NGOs are described elsewhere in this report (p13).

Although Agihas is a member-based, PLHIV group, its membership is relatively small, around 20, and is drawn particularly from men who have sex with men. There seems be limited representation of particular sub-groups of PLHIV including IDUs, ethnic Russians and women. There appears to be a view that NGOs that provide services to particular populations can represent their interests. However, they do not appear to have explicit mechanisms to do this.

Although PLHIV are involved in the State Commission, their influence on decisions is quite limited.

ARV drug procurement and prices

In 2008, Latvia's budget for ARVs was Lats 2.9 million but this budget for 2009 has been reduced to Lats 2.1 million (see Table 2, p16). However, Table 1 indicates that the annual cost of ART is only Lats 1.76m[25]. This figure is for ARVs only and does not take into account the need for other drugs and diagnostic test.

Based on the figures quoted in Table 1 of 313 people on treatment at a total cost of Lats 1.76m, the average cost of ART per year is Lats 5,620 per person. However, average costs vary hugely depending on the regimen used. The most commonly used first line regimen[26] cost Lats 3,714 per person per year, whereas the average cost for first line treatment was Lats 4,150 per person per year. Average cost for second line regimens was Lats 7,858 per person per year and for salvage regimens was Lats 15,744 per person per year.

These treatment costs are very high when compared to other middle income countries (WHO, 2008). For example, in 2007, the average cost for first line drug

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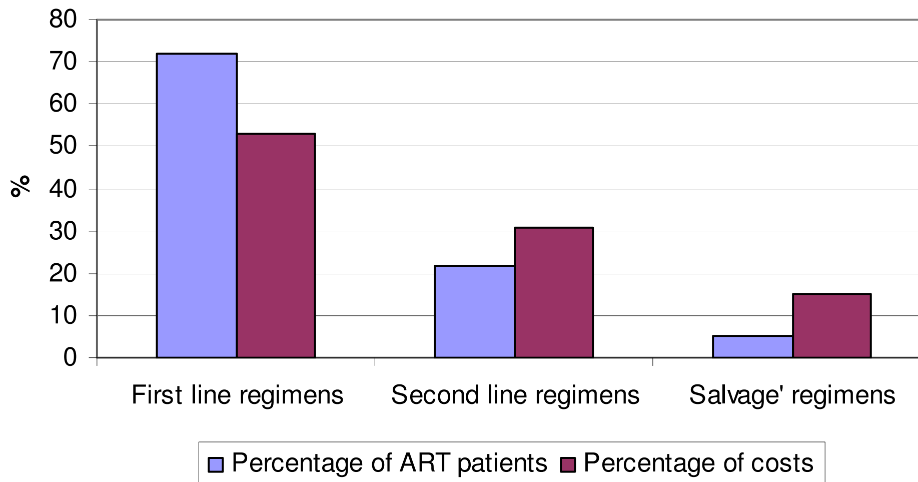
[22] Agihas
[23] Represented through Association HIV LV
[24] Dialogs
[25] Based on 313 patients on treatment as of March 2009
[26] Of EFV, 3TC and AZT which accounts for 61% of those on first line regimens

regimens was only US$357 per person per year. In Latvia, it was over US$7,500. Similarly, in middle income countries, in 2007, the average cost for second line drug regimens was US$3,306, whilst in Latvia it was almost US$15,000. However, it is recognized that some middle income countries may be able to achieve lower prices than Latvia because they are recipients of money from the Global Fund or because they use high volumes of ARVs. In addition, Latvia, as a member of the European Union is part of a single market, and therefore experiences higher price levels for these patent-protected medicines.

Nevertheless, although almost three quarters of patients (72%) were on first-line treatment, these only accounted for just over half (53%) of spending on antiretroviral drugs. Less than one quarter of patients (22%) were on second line treatment yet these accounted for almost one third (31%) of spending on antiretroviral drugs. 'Salvage' regimens are particularly expensive. Only 5% of patients were on these regimens but they accounted for 15% of spending on antiretroviral drugs (see Figure 5). In addition, there are concerns that people living with HIV in Latvia may be being placed on second line and 'salvage' regimens too soon. If true, this has significant cost implications.

Figure 5: Comparison of percentage of ART patients and percentage of costs for different ARV regimens[27] in Latvia (from data in Table 1)



Currently, procurement of ARVs is handled on an annual basis by the Centre of Infectious Diseases and the State Compulsory Health Insurance Agency. There are some concerns that:

[27] As defined by WHO. These regimens may not be being used in this way in Latvia. For example, regimens reserved by WHO for second line therapy may be being used as first line regimens in Latvia. This has significant cost implications as illustrated in this figure.

- This mechanism does not benefit from the expertise of the Medicines Pricing and Reimbursement Agency which negotiates prices for other pharmaceuticals based on economic evaluations

- This mechanism has not been subject to the same cost-containment measures applied to other pharmaceuticals (Tragakes et al., 2008)

- Price may not be being given sufficient weight in current tendering procedures with reports of tenders being awarded to suppliers who did not necessarily offer the lowest price

- Drugs are being purchased in very small volumes because of the multiplicity of regimens available to patients

- Legislation restricting purchase of drugs direct from manufacturers is resulting in higher prices

There are plans to decentralize procurement of drugs to specific hospitals because current mechanisms are considered cumbersome. However, there are concerns that economies of scale may be lost and that technical and administrative capacities of these hospitals may be limited. Although there are limits on the price allowed for reimbursement of outpatient drugs, this does not apply to inpatient drugs. In addition to the standard procurement mechanisms, hospitals or the state can directly import drugs under certain circumstances and patients can also import medicines for their own personal use. These mechanisms could be explored as alternative supply channels, as they would allow for direct cheaper imports with approval of the State Agency for Medicines.

There are disturbing reports that some people living with HIV are being denied access to treatment in order to keep treatment numbers within the allotted budget. Estimates vary but it is estimated that perhaps 700-1200 people currently need treatment (see p11). This number is likely to increase in the future. At current costs, treatment for this number of people would cost around Lats 3.9m to 6.7m. Since it is very unlikely that such amounts of money will be allocated, ways need to be found to reduce the cost of ART. To treat 700 people with funds available in the 2009 budget would require almost a 50% reduction in the cost per person per year, from Lats 5,620 to Lats 3,000.

Considerable savings could be achieved by greater uniformity in prescribing practice, reducing the number of different regimens offered and keeping people on first line regimens longer. However, there also needs to be reductions in price paid for ARVs. Mechanisms for this might include:

- Simplifying and clarifying regulatory systems for ARVs, e.g. by
    - ensuring that all drugs in treatment guidelines are included in the national reimbursement list

- merging the current out-patient reimbursement list and the hospital medicines list

- Allowing registration of more ARV products in Latvia to increase competition. However, incentives for manufacturers to register their products in Latvia are relatively limited as it is a small market. But, most ARVs are registered in Latvia through a centralized EU system.

- Direct price negotiation based on international price benchmarking. A useful source of information for this is the 2008 survey of ARV prices in European countries. Although direct comparisons are not easy[28], it appears that Latvia is currently paying low prices for some drugs, e.g. efavirenz but high prices for others, e.g. zidovudine. In addition, the Medicines Pricing and Reimbursement Agency is part of several European networks of medicines pricing and reimbursement authorities and has access to up-to-date information on the ARV prices that other European countries are paying. This is probably the most effective mechanism available to obtain lower ARV prices.

- Using TRIPS flexibilities to allow importation of generic products. It is currently unclear to what extent this would be permissible in Latvia. A preliminary review of the 2007 patent law would seem to reveal limited possibilities for this. However, a more detailed review might be helpful. Latvia might consider inserting 'Government Use' powers into its patent law, which allows use of a patented medicine in public, non-commercial programmes without the permission of the patent holder[29]. Particular consideration should be given to using generic versions of early ARVs as patent rights may no longer apply to these medicines developed in the late 80s and early 90s.

However, there are also some factors which may result in increasing ARV prices, such as a planned 5% increase in VAT in early 2009. Another area where cost savings could be made is in the monitoring of ART. For example, a World Bank study (Alban and Miezitis, 2007) estimated that ART monitoring costs Lats 334 per person per year. This is higher than for other countries in the region. There are concerns that actual figures for 2008 are even higher[30] and that they are even higher in prisons[31]. Areas where savings could be made include:

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[28] Because of different dosage forms, pack sizes, tax rates etc. and provision by companies of non-transparent discounts

[29] However, as a result of the new EU member states opt-out of the WTO 'August 30th' decision, it is more difficult to find foreign sources of such generic medicines

[30] It is reported that the total expenditure on ART monitoring in 2008 was Lats 181,808. Assuming a maximum of 450 PLWH receiving treatment during that period, the cost per person per year would be Lats 404.

[31] It is reported that the total expenditure on ART monitoring for prisoners in 2008 was Lats 14,712. Assuming 25 prisoners on ART, this is a cost of Lats 589 per person per year.

- A more cost effective strategy for testing drug resistance
- More rational use of viral load testing

Access to HIV Treatment and Care, Coverage and Quality of Services.

Health care of PLHIV

Many of the issues relating to the health care of people living with HIV have been covered earlier in this report (see p9). There are specific concerns about the provision of services to HIV positive pregnant women for the prevention of mother to child transmission. Results from 2006 to 2008 show high transmission rates of 29-62%[32]. Reasons for this might included limited availability of VCT for pregnant women, poor quality of counselling for pregnant women, limited funding for PMTCT and weak adherence support for pregnant women, particularly IDUs, on ART.

Psychosocial support to PLHIV and case management

Psychosocial support is important for people living with HIV, particularly in relation to initiating and adhering to ART. Some psychosocial support is available to PLHIV in Latvia, particularly through support groups and consultations with psychologists. However, these services are currently limited in scale and the linkages to ART provision could be stronger. For example, such provision would be stronger if a psychologist or NGO support services were available at the Centre of Infectious Diseases.

Physical accessibility to treatment

The biggest issue relating to access to treatment is that ART is currently available at one location in Latvia (see p14).

There are also issues regarding access to treatment for those in the prison system. Some general details of the prison health system are provided elsewhere in this report (p15).

Based on data from the Ministry of Justice supplied to the team, it appears that there are a total of 445 PLHIV in prisons. Of these, 380 (85%) are men and 65 (15%) are women. Almost all (95%) of the people living with HIV in prisons have a history of injecting drug use. Although, in principle, ART is available in prisons to those who need it, it appears that very few receive this, in practice. Figures provided to the team were that a total of 24[33] prisoners were receiving ART at the time of the visit. This is only 5% of people known to be living with HIV in prisons.

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[32] In 2006 5 out of 17; in 2007 8 out of 13; and in 2008 8 out of 13

[33] The figure of 25 was also cited in some team reports

Of these, 19 (79%) were male and 5 (21%) female. ARV treatment interruptions have also occurred in prisons, as in the community. However, there are broader problems about the availability of essential medicines in prisons, e.g. shortages of insulin are reported. The main reason for this is that the prison system has to buy medicines from its own health budget. The reimbursement system that operates in the community does not apply to prisons.

In principle, prisoners are entitled to free HIV/AIDS and TB treatment. However, they are requested to pay the full price for certain types of care and drugs, including treatment of opportunistic disease.

Reasons for the relatively low uptake of ART in prisons are varied, including limited funds for ART and a 'lack of knowledge' among HIV positive prisoners[34]. There are also problems with availability of support services required for ART. Financial issues mean that, in 2009, HIV testing on entry into the prison system was suspended. Services for injecting drug users, such as the provision of methadone and/or sterile injecting equipment, are not available in Latvian prisons. However, it is reported that methadone maintenance therapy in prisons is included in the new national AIDS programme and there are reported plans to begin a pilot of this in one prison soon.

Principles of equity and non-discrimination

Although the majority of those living with HIV in Latvia acquired the virus through injecting drug use, less than a third (32%) of those on ART have a history of injecting drug use. Significant challenges are faced by HIV positive IDUs in accessing ART in Latvia. These include:

- Highly stigmatizing attitudes towards IDUs among health professionals. Such attitudes are also witnessed among some NGOs

- Strict rules in the Centre of Infectious Diseases regarding access to ART which effectively exclude IDUs. For example, it was reported that the centre regards drug use as a contraindication to ART and does not offer treatment of withdrawal symptoms

- Limited availability of opioid substitution therapy. Methadone maintenance treatment is financed from a state programme but is only available at two sites[35]. Buprenorphine is only available as a paid service[36]. Many IDUs

[34] It is unclear if this has been assessed rigorously.
[35] Until 2008, methadone maintenance therapy was only available in Riga. In 2008, 103 patients received treatment. In January 2009, a second site began operating in Jelgava.
[36] Patients wishing to receive buprenorphine need to meet all the costs of this. At the time of the visit, it was reported that around 15 patients were receiving buprenorphine.

face interruption in their methadone because of arrest and non-availability of methadone in the criminal justice system[37]

- Lack of collaboration between the Centre of Infectious Diseases and the Riga Psychiatry and Addictions Centre

- Non-integration of opioid substitution therapy and ART, i.e. they are not provided in the same location. Although the Centre of Infectious Diseases employs an addiction specialist, he has no experience of methadone maintenance

- Excessively restrictive practices regarding admission to and participation in methadone maintenance treatment programmes, e.g. the absence of take-home policies

- Very limited focus on adherence support for PLHIV, in general, and IDUs, in particular. Although NGOs provide information on ART on their websites and in information sheets, they are currently not directly involved in educating and supporting IDUs to take ART

- Missed opportunities for HIV diagnosis among IDUs. For example, patients with hepatitis B and C are not routinely offered HIV tests

However, IDUs face even more severe challenges in accessing other forms of treatment. For example, treatment for hepatitis C requires a 50% co-payment, which makes it impossible for most IDUs[38].

It is of particular concern that these systemic barriers to IDUs accessing ART are not well-recognised in Latvia. Rather, IDUs themselves are usually blamed for not taking up or not adhering to treatment services.

Compliance with WHO clinical protocols and good practice

Latvia's performance is relatively weak in this regard. Specific areas of concern include:

- Use of too many different ART regimens without adequate explanation

- Excessive, early use of ART regimens which WHO recommends for second line and 'salvage' use

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[37] For example, it was reported that 12/103 people on methadone in Riga stopped treatment in 2008 because of imprisonment. A study by Dialogs (Dialogs, 2007) found that more than half (51%) of IDUs had been imprisoned at least once.

[38] Figures supplied to the team indicate that of 4,369 PLWH, 1,844 are known to also have hepatitis C infection.

- Inappropriate use of resistance testing. Between 2006 and2008, Latvia conducted 259 drug resistance tests[39]. This is many more than would be needed for a threshold survey. However, these were not conducted as part of such a study, so the findings lack statistical power and should not be used for this purpose.

  There is currently no system for HIV drug resistance prevention, monitoring and surveillance. This would require a focus on early warning signs by monitoring:

  - Prescribing practices, the percentage of those receiving standard first line or second line regimens
  - Patients lost to follow up twelve months after starting ART
  - Patients still on first line therapy twelve months after starting ART
  - Percentage of patients picking up all their prescribed ARVs on time
  - Percentage of patients keeping their appointments
  - Pill count/adherence
  - Continuity of drug supply and avoidance of stock-outs

  WHO recommends forming a national committee or working group on HIV drug resistance. This should include experts responsible for HIV surveillance, HIV care and treatment and an HIV drug resistance laboratory. Specific action points for this group are listed in Annex 3 (p**Error! Bookmark not defined.**).

  WHO does not recommend individual HIV drug resistance testing until a national HIV drug resistance strategy is in place. Testing for treatment decisions is only needed if the second line treatment fails without an identified reason[40] (WHO, 2009).

Independent quality assurance schemes for services are not yet established. In order to improve quality of services provided, the emergence of hepatitis C as a serious public health issue has to be addressed. Currently, hepatitis C is only treated as part of the state programme if the patient has voluntary health insurance. This is problematic because most cases of hepatitis C occur among IDUs. The majority of IDUs are not covered by voluntary health insurance.

Monitoring, evaluation and quality assurance systems

Currently, no public health analysis is conducted from the individual patient records, including analysis of:

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[39] The basis on which these tests were performed is unclear. For example, it is not clear if they were performed in those who already failed an ART regimen or in patients before initiation of ART. This limits the usefulness of the results.
[40] Such as poor adherence or adverse drug reaction/interaction

- ARVs used as the first line regimen
- History of different regimen use
- Duration of first line treatment after its initiation
- Reasons and time after initiation of treatment for regimen switches
- Drop-out rates and reasons
- Follow-up
- Compliance
- Death rates

However, a national patient monitoring system, such as the one that exists in the Netherlands, would be possible in Latvia, because of the small size of the country and the patient numbers. Since a lot of different treatment schemes have been used in Latvia, it would be a good opportunity to compare the outcomes of different regimens.

CONCLUSIONS

In order for a country to provide essential HIV-related services, including ART, it needs structures in place to allow effective leadership of the national response to HIV and AIDS. Such structures are not fully developed In Latvia. Stronger leadership is needed from the Ministry of Health and the State Commission on HIV and TB. Planned reforms to bring the prison health system under the management of the Ministry of Health are much needed. There is a need to urgently approve the new national HIV programme and its budget.

It is of grave concern that ART is currently only available to just over 300 people when the estimated need is between 700-1200. A key bottleneck in this regard is that AIDS treatment, care and monitoring is only available in one centre in Riga. In addition, there is a need to focus on addressing the high default rate among those who start treatment through NGO-delivered programmes of adherence support. There is also a need for services which make it easier for IDUs to receive ART. The single, most critical step in achieving this is to expand the availability of methadone maintenance treatment both in the community and in prisons. There is a need for such services to be delivered in a well-coordinated way with the provision of ART, ideally in a common location.

Another concern is the unstructured way in which ART is currently being provided in Latvia. It is hard to explain why there are 67 different regimens for a relatively small number of patients. It is also unclear why so many PLHIV are on ARVs recommended by WHO as second line and 'salvage regimens'. Both these factors are resulting in an extremely inefficient use of resources. The average cost of ART is higher in Latvia than in other comparable countries. Alternative procurement practices need to be explored as they can lead to considerable savings.

There is currently unequal access to ART for different people in Latvia. In particular, it is more difficult for IDUs to receive ART than for non-IDUs. The most significant barrier to this is the very limited availability of methadone maintenance therapy and its complete non-availability in prisons. In addition, stigma and discrimination towards IDUs is widespread in Latvian health services. Financial barriers mean that unofficial 'quotas' are being operated as to who can receive ART. This is particularly problematic within the prisons.

Currently, patient monitoring is excessively focused on individual patient records with little aggregation of data for public health purposes. In addition, there is excessive reliance on inappropriate resistance testing in the absence of a fully-developed HIV resistance prevention and monitoring system.

Finally, there is relatively little integration of services. This applies both within government services, e.g. TB, HIV and drug services, and between government and NGO services.

RECOMMENDATIONS

1. **Speed up the institutional reform of state agencies** including revisiting the topic of prison health reform and the early adoption of the new national HIV programme. Part of this process included defining more clearly the roles and responsibilities of different bodies.

2. **Scale up access to ART** by decentralizing treatment outside of Riga through involving infectious diseases specialists of regional medical centres, involving NGOs in the provision of adherence support and coordinating more closely with essential services for IDUs, such as the provision of methadone maintenance therapy.

3. **Promote more rational use of ARVs** by reviewing the ARVs on the national drug list and merging outpatient and inpatient lists.

4. **Adopt a more public health focused approach to ART**. In particular, this would involve specifying:

    - The ARVs to use in first line, second line and 'salvage' regimens
    - Criteria to start ART
    - Criteria to switch regimens
    - Criteria for substitution of one ARV with another one.

    This would require revision of the national guidelines in accordance with the WHO European Region clinical protocols on HIV/AIDS Treatment and Care. More training of health professionals is required focused on consistency of practice and efficient use of resources.

5. **Obtain lower ARV prices** by better procurement practices including increasing scale of purchases by reducing number of different regimens offered, using price comparison data in negotiations and direct purchasing from manufacturers abroad using existing legal mechanisms. Other options, such as using generics where patents have expired and where public health concerns merit it, should also be considered.

6. **Take steps towards more equitable access to ART**, particularly among IDUs. The most significant step that could be taken would be scaling up methadone maintenance treatment in the community and prisons. Measures are also needed to address stigma and discrimination experienced by IDUs in Latvian health services.

7. **Adopt a more public health focused approach to patient monitoring.** This will involve more aggregation of key data which would be made easier by the introduction of an electronic patient database. HIV resistance testing needs to be part of a more well-developed system on drug resistance, based on threshold surveys on transmission of drug resistance and observational cohort analysis of prevalence and incidence of resistance. Implementation of drug resistance tests at individual level is recommended after 2nd line ART failure. This will improve practice and offer cost savings.

8. **Promote greater integration of services.** In particular, this should focus on TB, HIV and drugs services. A big step forward would be co-location of ARV and methadone maintenance treatment. Greater integration of government services with those provided by NGOs, e.g. on ART adherence, would be welcome.