

**Opioid Substitution Therapy (OST) with
Buprenorphine in Ukraine – Way to Prevent
HIV/AIDS among IDUs**

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**4th IAS Conference on HIV Pathogenesis,
Treatment and Prevention**

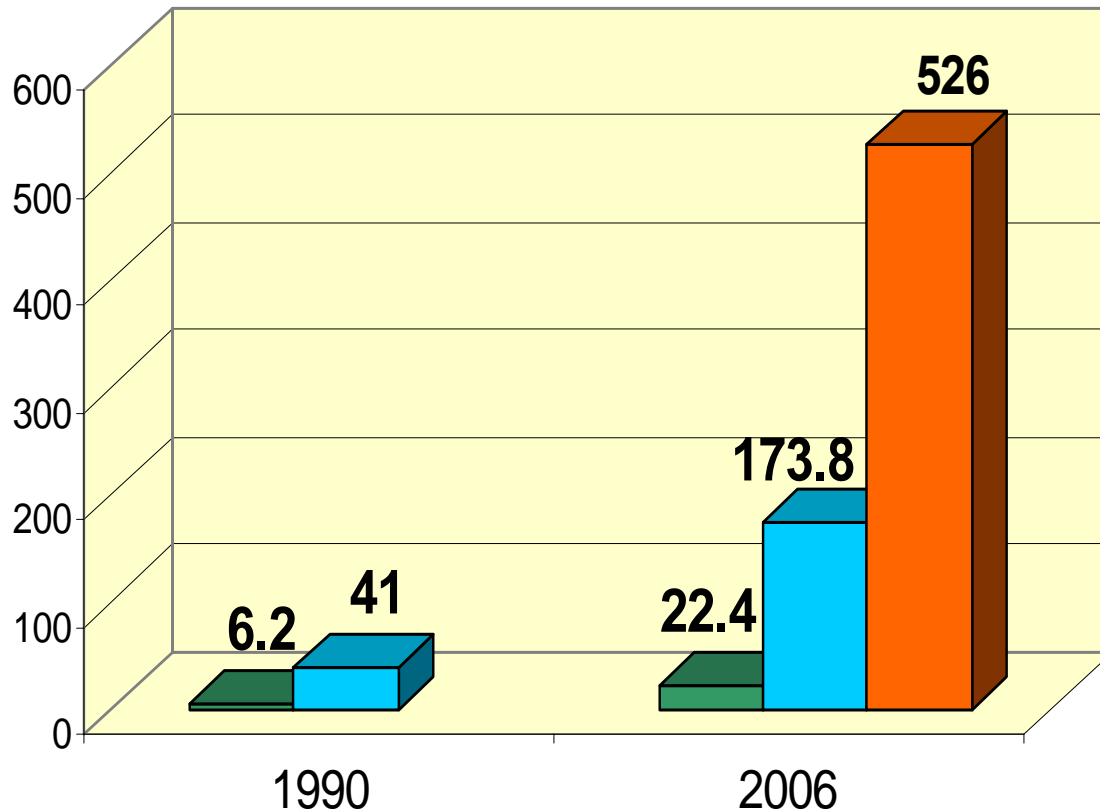
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Drug statistics in Ukraine, 1990-2006



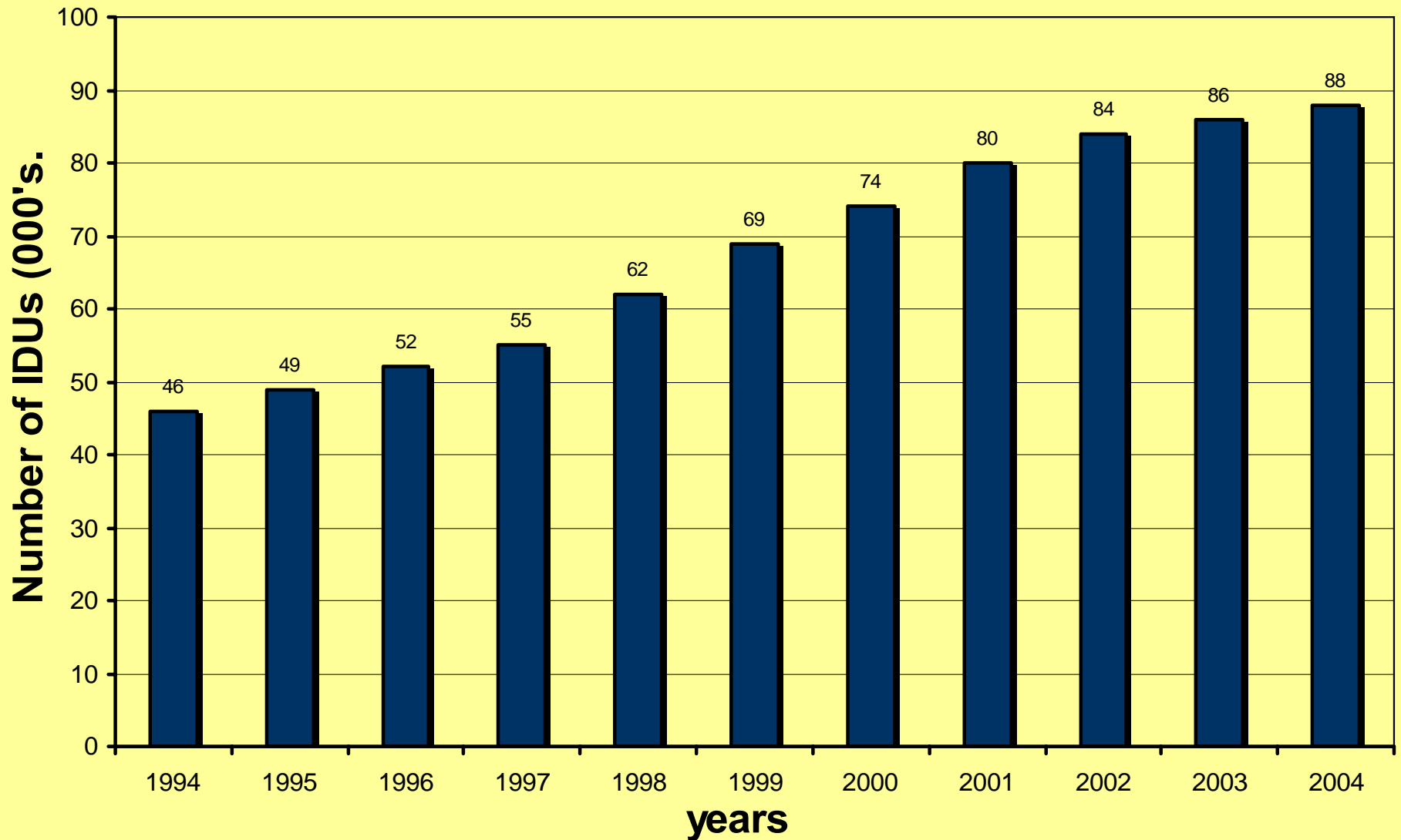
- Official Incidence of drug-related disorders per 100'000
- Official Prevalence of drug-related disorders per 100'000
- Estimated prevalence of IDUs per 100'000 (UNAIDS)

No IDU size estimations were held in 1990;

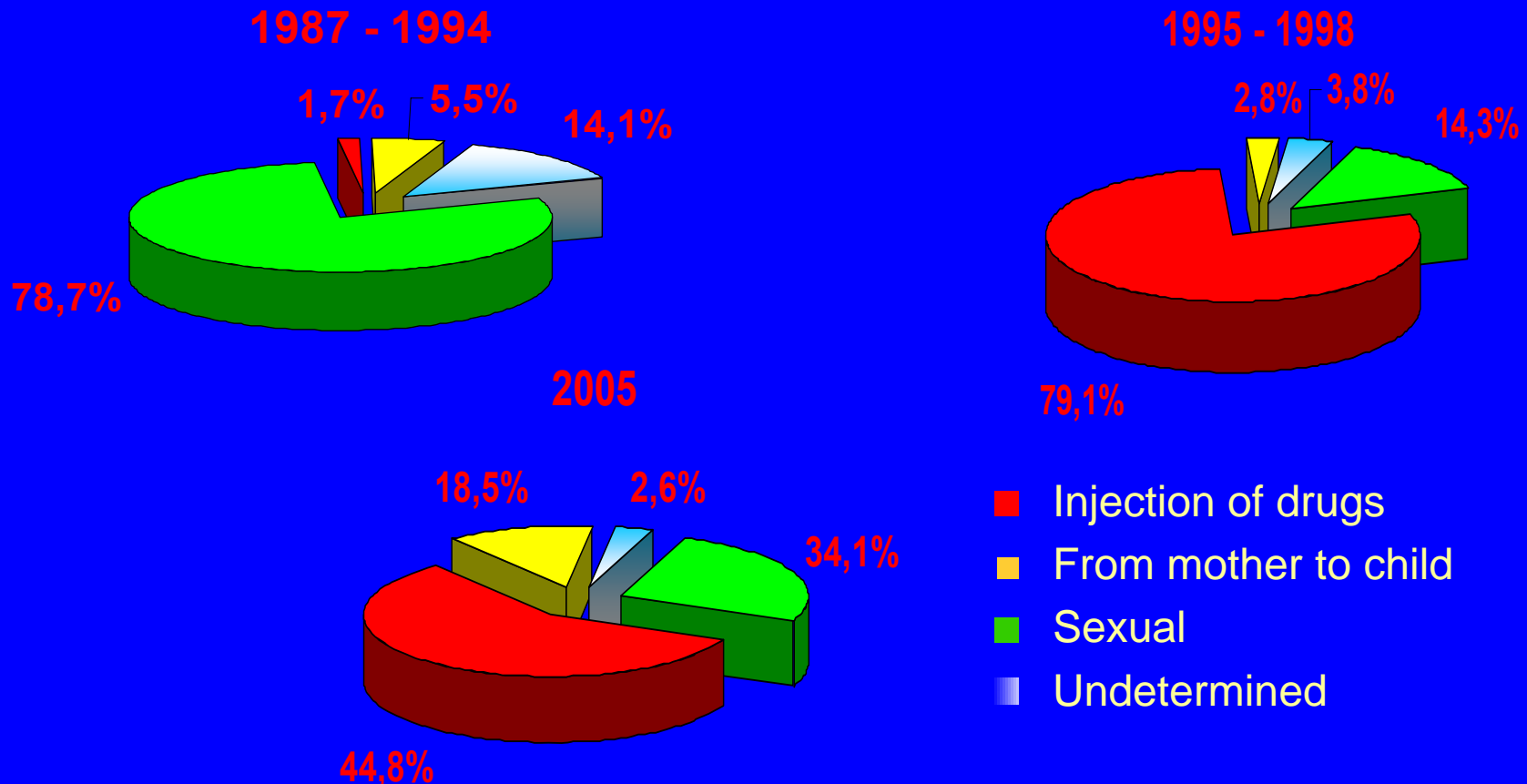
Number of individuals officially registered with drug-related disorders was **123'400** in 2006;

Estimated number of IDUs in Ukraine (2005-2006) is **325'000 – 425'000**

Prevalence of IDUs in Ukraine (MoH data)



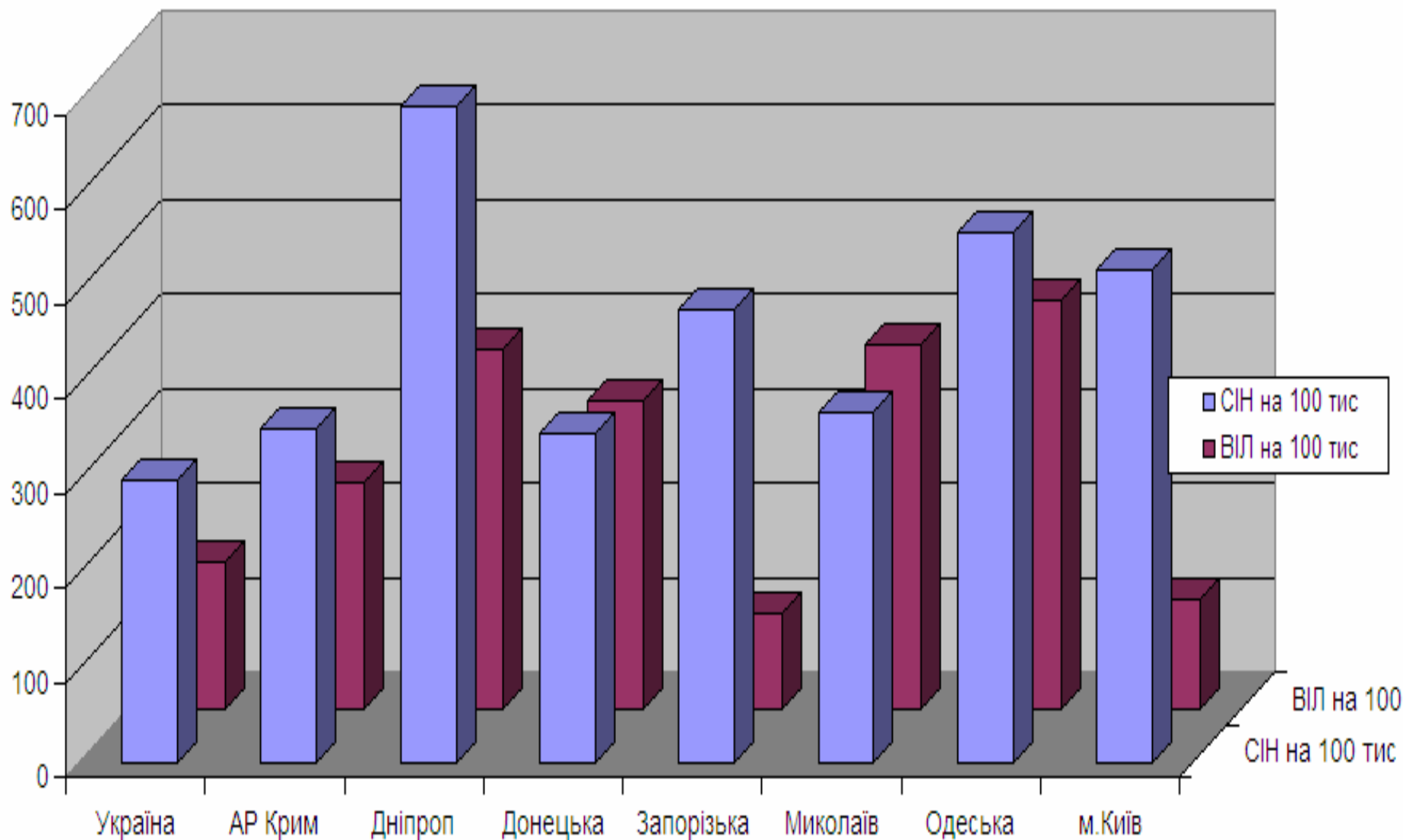
HIV transmission in Ukraine



*Note: Practices of HIV testing among IDUs, people with STDs, pregnant women and blood donors had been changing in 1996-2003.

Data of the Ukrainian AIDS Center

Relationship between IDU and HIV



Political context

POSITIVE

- National program of HIV/AIDS Prevention & Treatment (2002)
- National Concept 2004 – 2008 on HIV/AIDS Pr. & Tx (2004)
- National Standards of the Narcology Help (1998)
- Resume of Parliament hearings (2004)
- Results of pilot projects & number of scientific papers (2000-2006)

NEGATIVE

- Official response regarding to SMT by SSU
- Official position of MIA
- Many articles in mass-media
- Many oral statements of politicians in media
- Number of semiprofessional opinions in press
- Statement of the Ministry of Health: “SMT is a not our way!”

**Joint Mission of WHO/UNAIDS/UNODC
on SMT in Ukraine
(November, 2004)**

- *~ 30-40% of IDUs depended from opiates should have access to SMT for get influence on both epidemics – drug use and HIV.*
- *For Ukraine, where estimated number of IDUs is 325 – 425 thousands, the need in SMT is between 60 - 200 thousands courses*

UNDP Pilot Project. SMT with Buprenorphine (Addnok) 2004-2005

- **Kyiv** – 57 clients (2 fem.)
- **Kherson** – 30 clients (1 fem.)

CRITERIA:

1. Opioid dependence (ICD-10).
2. Two or more previous unsuccessful treatment attempts (drug-free)
3. 18 or older
4. Readiness for the program

WHO-multi-site prospective study Evaluating the Efficacy of ST in Opioid Dependence and HIV/AIDS

- **Robert Ali** - *Australia*
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- **Linda Gowing** - *Australia*
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- **Azarakhsh Mokri** - *Iran*
- **David Newcombe** - *Australia*
- **Vladimir Poznyak** - *WHO Geneva*
- **Emilis Subata** - *Lithuania*
- **Ambrose Uchtenhagen** - *Switzerland*
- **Chengzheng Zhao** - *China*

Overview of the Study

- This was a prospective observational study with assessments at baseline, and 3- and 6- month follow-ups
- All assessments are related to the period of one month prior to interview
- The main aims of **outcome** evaluation were to explore changes in the following domains:
 - Health Status and well being of individuals in substitution treatment,**
 - Community/ Social benefits,**
 - And also Programme performance**

General Protocol of the Study (2003)

Dr. Vladimir Poznyak, Management of Substance Abuse, Department of Mental Health and Substance Abuse, WHO, Geneva

Professor Ambros Uchtenhagen, Research Institute of Mental Health and Addiction, Zurich, Switzerland

Professor Robert Ali, WHO Collaborating Centre for the Treatment of Drug and Alcohol problems, University of Adelaide (Australia)

- *Data collection Sites/ Clinics involved in the study:*

1. Regional Narcology Dispensary of Kherson Region;

2. Kiev City Narcology Hospital

- *State data collection time frame:*

1. April 2004 – December 2004

2. December 2004- May 2005

Demographics, Drug Use & Treatment History

Demographics at treatment entry

Participants (n)	76
Gender (% male)	89.5%
Age (mean, range)	30.61 (47-21)
Marital status (% married & co-habiting)	17.1% & 19.7%
Years of education (mean, range)	12.58 (19-8)
Living arrangements (% own home)	75%
Mean age first opioid use	18.45 (33-14)
Most common opioid drug first used	Poppy straw
Percent (%) seropositive for HIV	N/A
Percent (%) seropositive for Hep C	N/A

Drug Use Lifetime (ASI – Lite)

	Mean (years)/SD/Range
Alcohol	13/7/33
Heroin *	1.2/2.6/10
Other opiates	10.3/6/33
Sedatives	1.05/2.5/16
Cannabis	6.6/6.9/27
Amphetamines (including ecstasy)	0.2/0.75/5

* Most common route of administration = intravenous

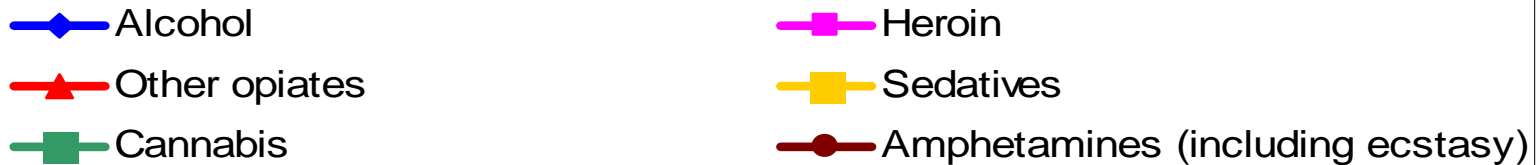
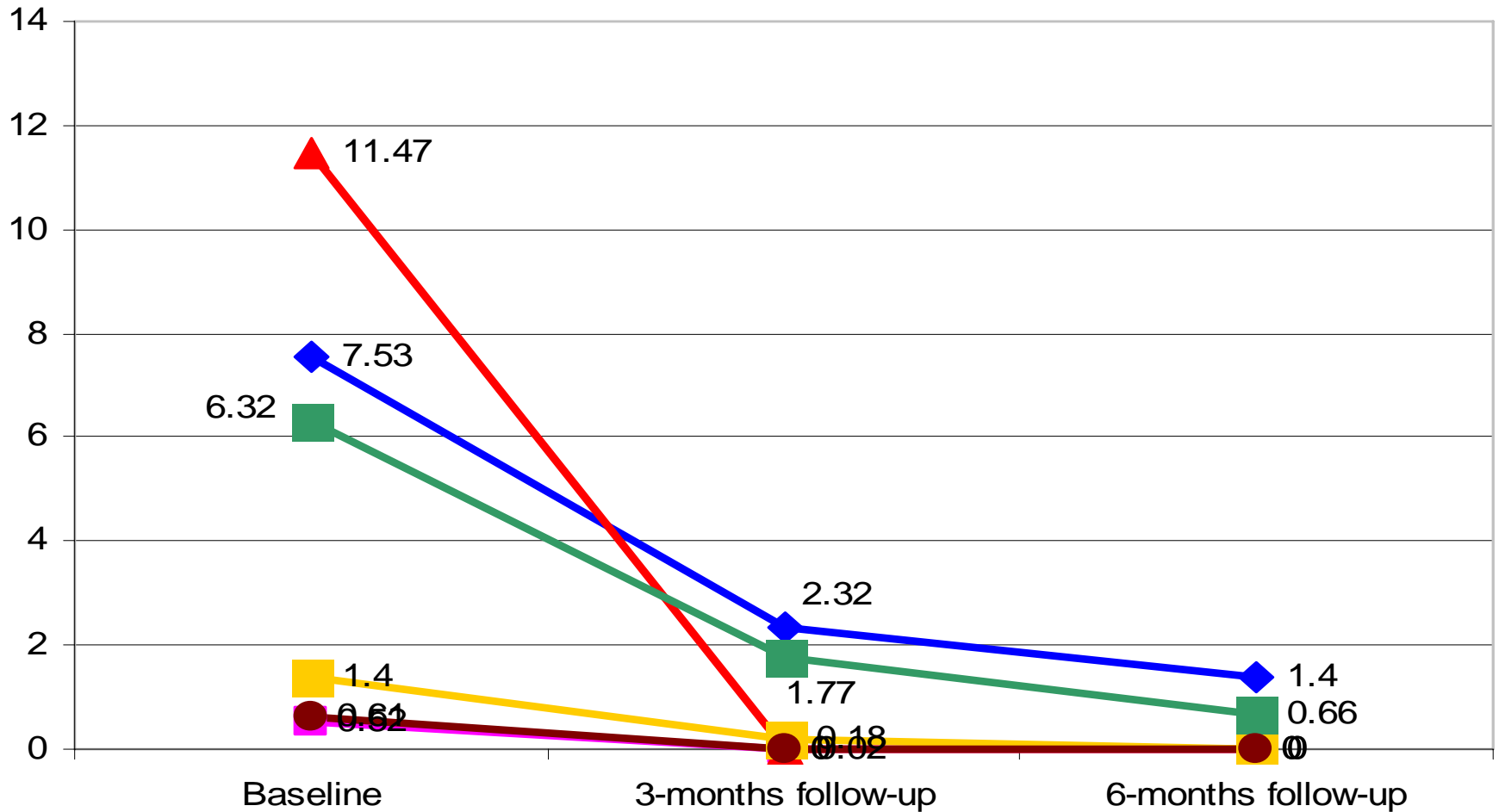
Changes in Well Being and Health Status and Social/Community Benefits

Some data from Poland and
Lithuania are demonstrated also

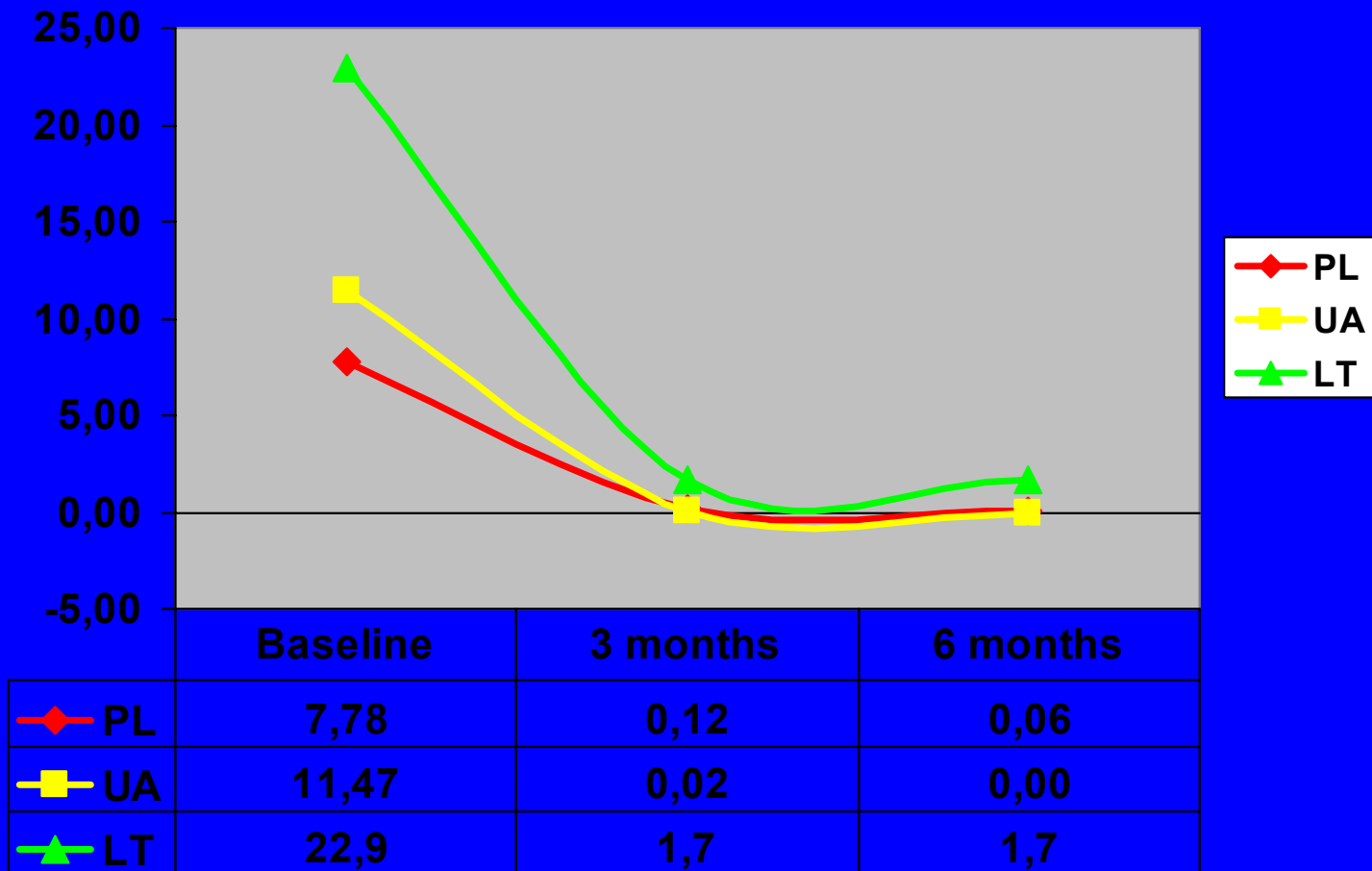
Drug Use last 30 days (ASI – Lite)

Mean \pm st. deviation (Range)	Baseline	3 months	6 months
Alcohol	7.53 \pm 8.13 (30 - 0)	2.32 \pm 4.7 (30 - 0)	1.4 \pm 2.15 (7 - 0)
Heroin	0.52 \pm 1.5 (8 - 0)	0 \pm 0	0 \pm 0
Other opiates	11.47 \pm 11.9 (30 - 0)	0.02 \pm 0.13 (1 - 0)	0 \pm 0
Sedatives	1.4 \pm 5.5 (30 - 0)	0.18 \pm 1.3 (10 - 0)	0 \pm 0
Cannabis	6.32 \pm 8.2 (30 - 0)	1.77 \pm 6.9 (30 - 0)	0.66 \pm 1.9 (10 - 0)
Amphetamines (including ecstasy)	0.61 \pm 3.7 (30 - 0)	0 \pm 0	0 \pm 0

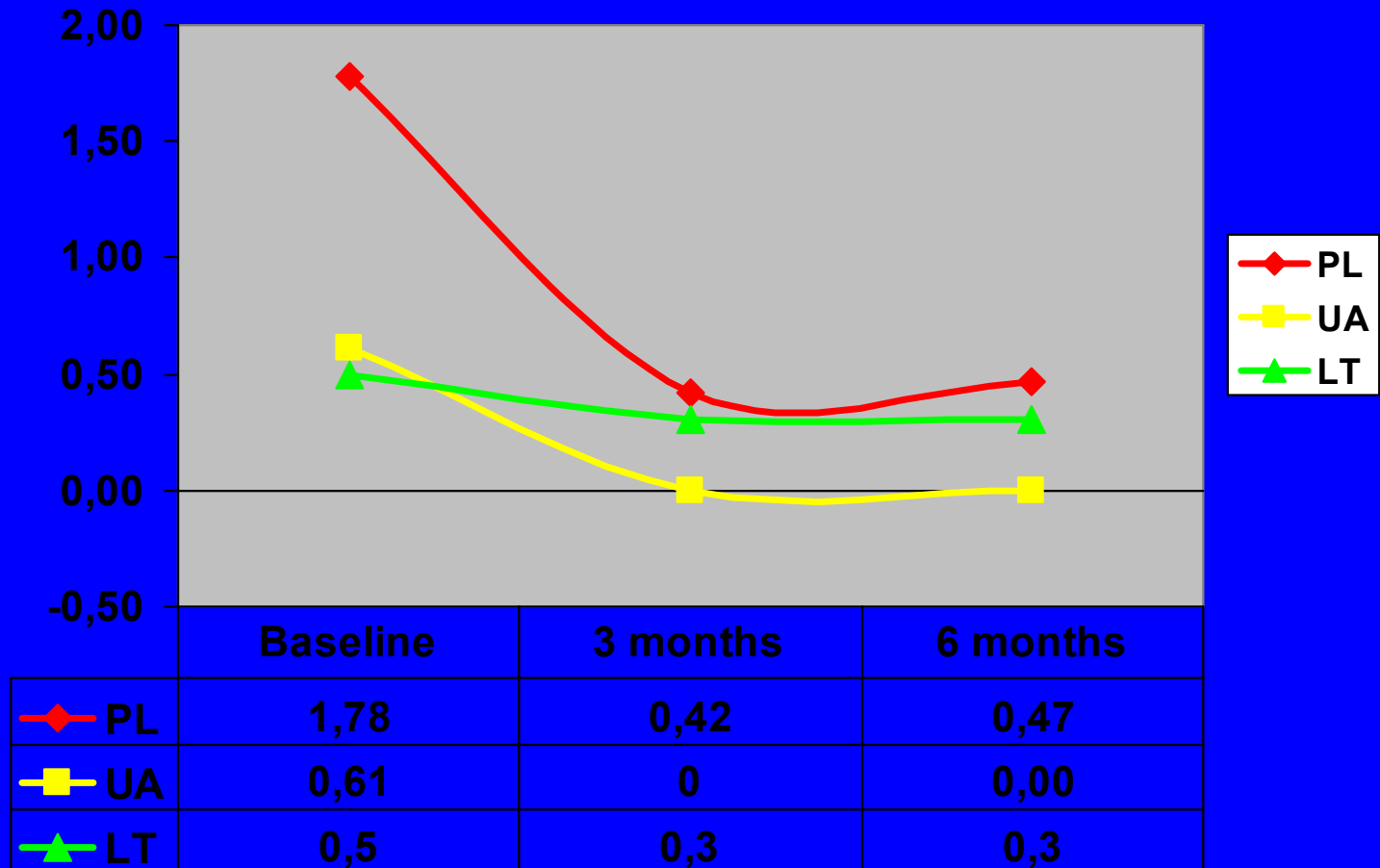
Drug Use last 30 days (ASI – Lite)



Other opioid (poppy straw) use in the last 30 days



Amphetamine use in the last 30 days



Health Status

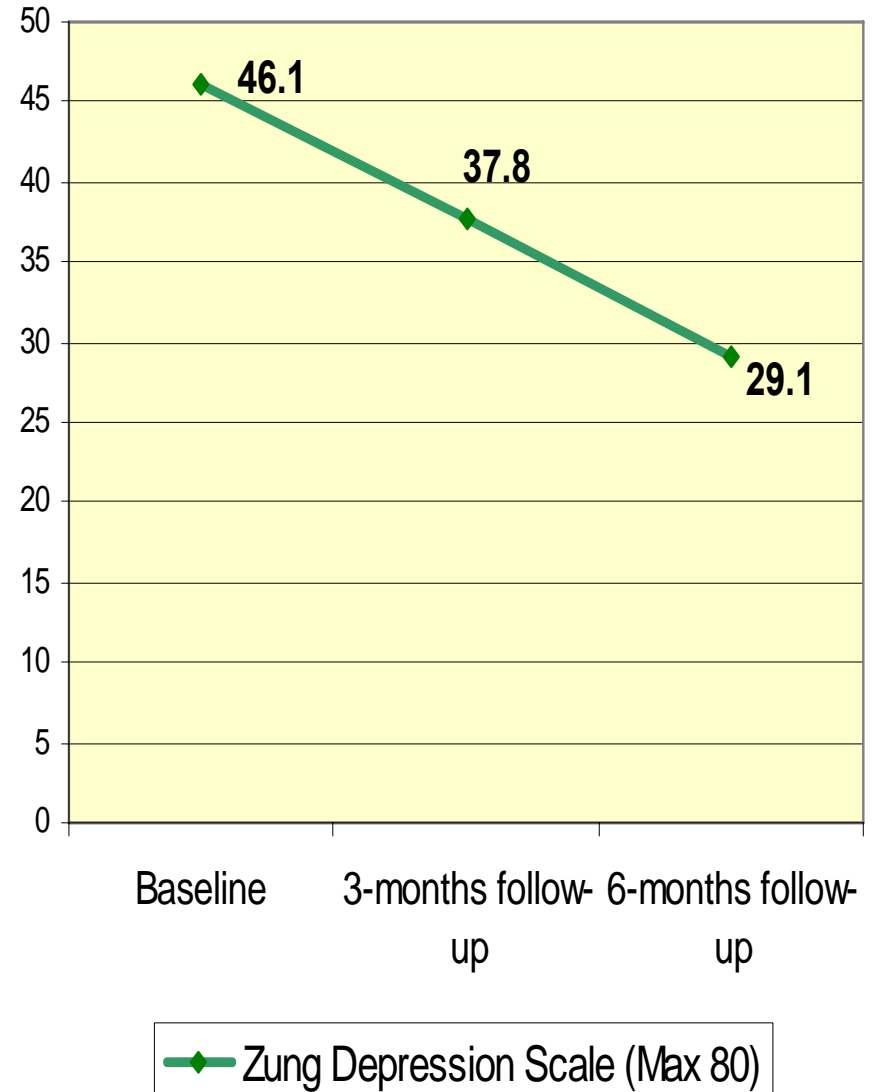
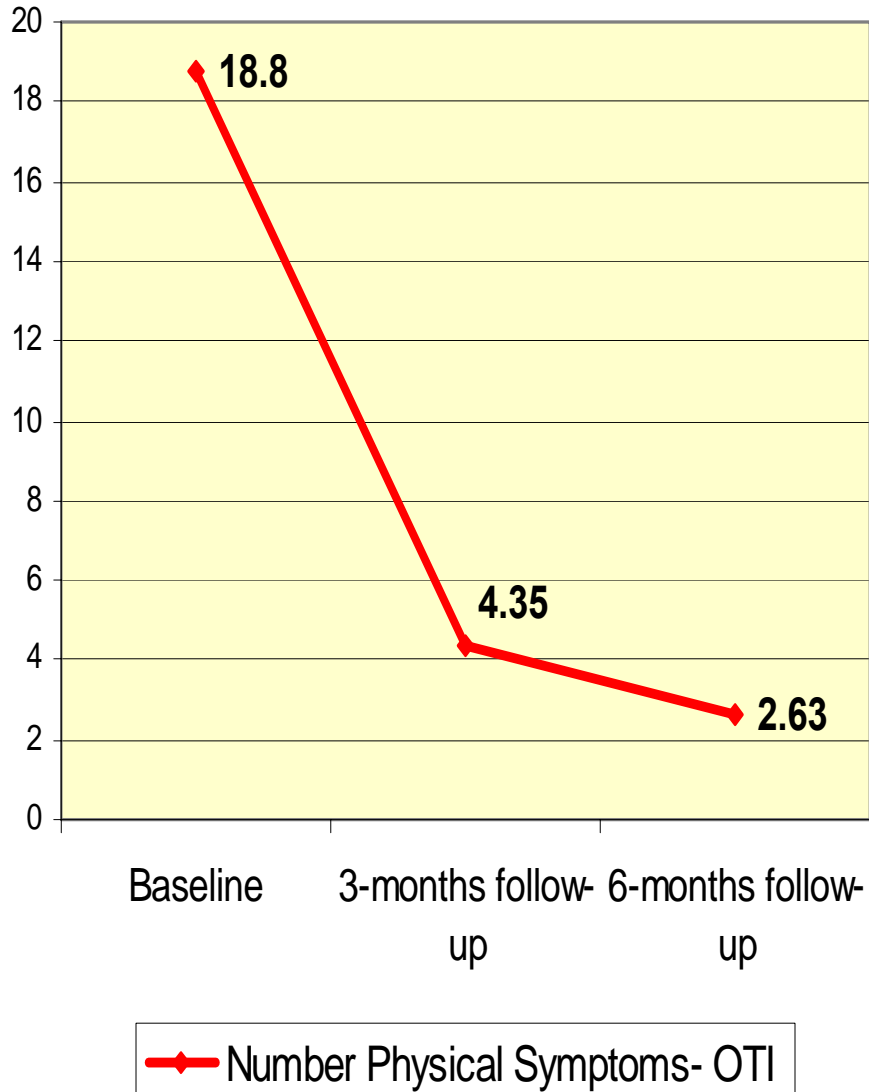
	Baseline	3 months	6 months
Number Physical Symptoms- OTI * [mean ± StD]	18.8±8.4 (39-2)*	4.35±3.3 (18-0)	2.63±3.9 (24-0)

* OTI-Opiate Treatment index – section three

Zung Depression Scale (Max 80) [mean ± StD]	46.1±11.3 (74-21)	37.8±11.8 (69 - 21)	29.1±7.2 (53 - 22)
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***Range**

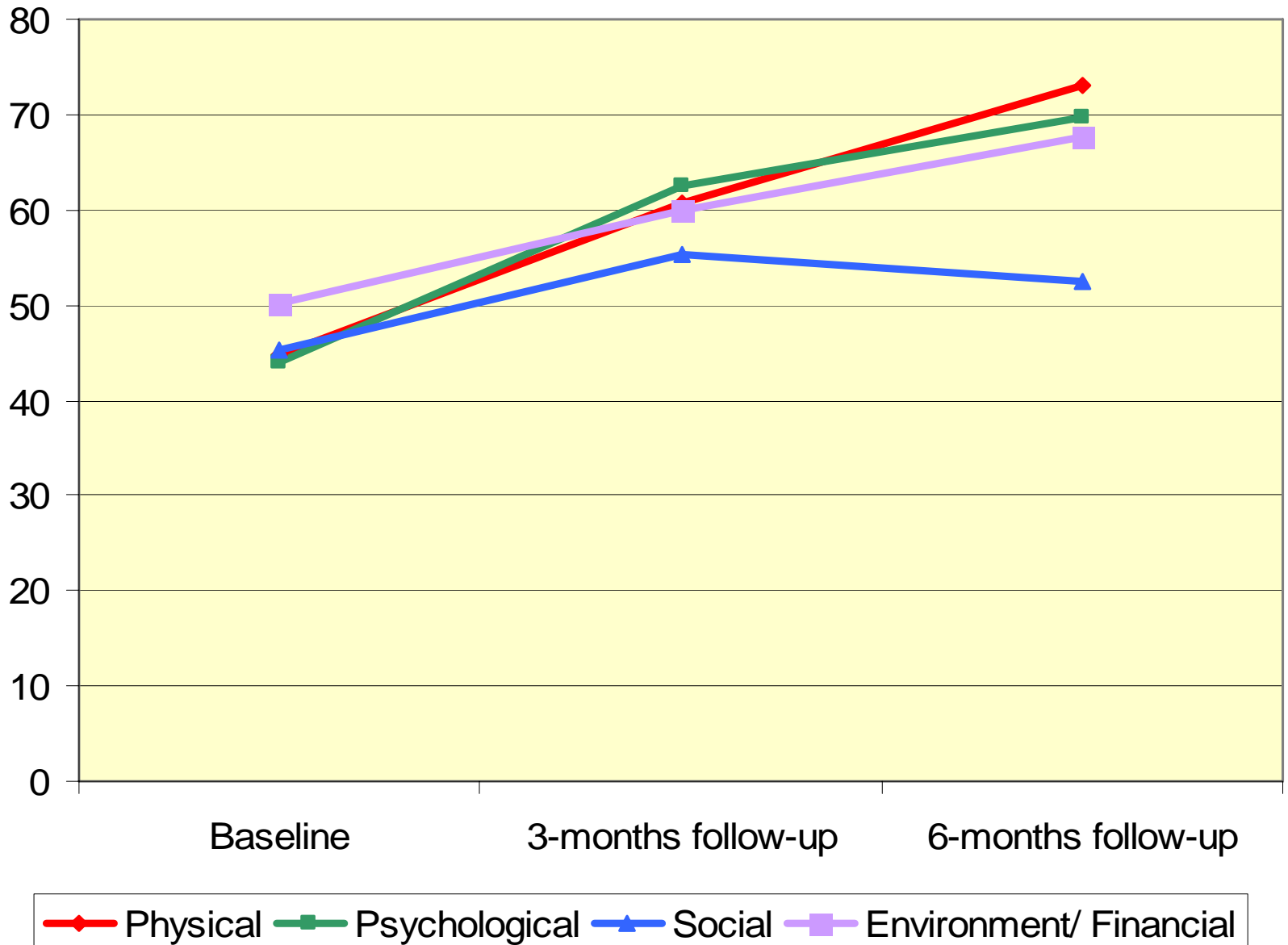
Health Status



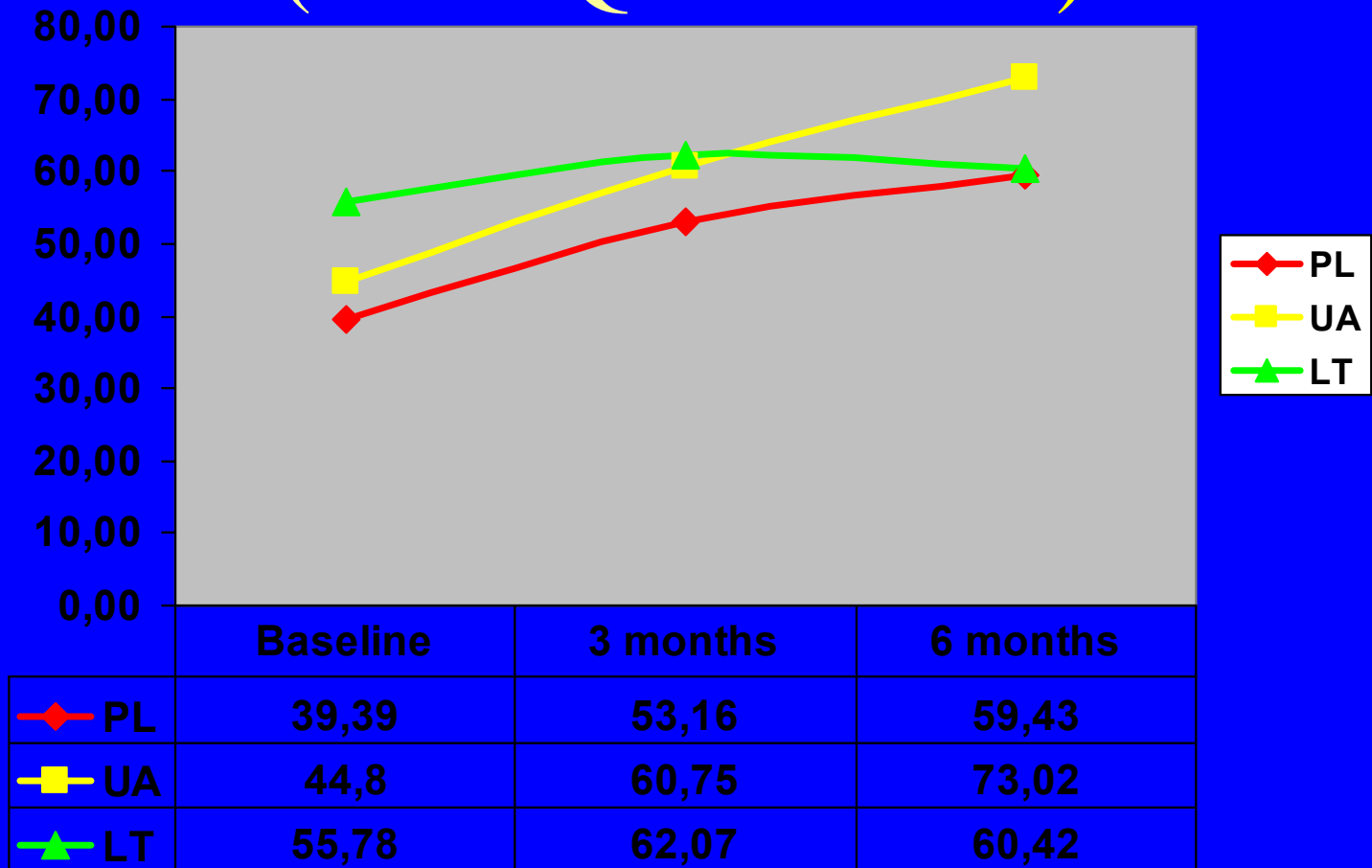
Quality of life: WHOQOL-bref

Domain [Mean Transformed score 0-100]	Baseline	3 months	6 months
1. Physical	44.8	60.75	73.02
2. Psychological	44.08	62.56	69.7
3. Social	45.4	55.25	52.4
4. Environment/ Financial	50.27	60	67.6

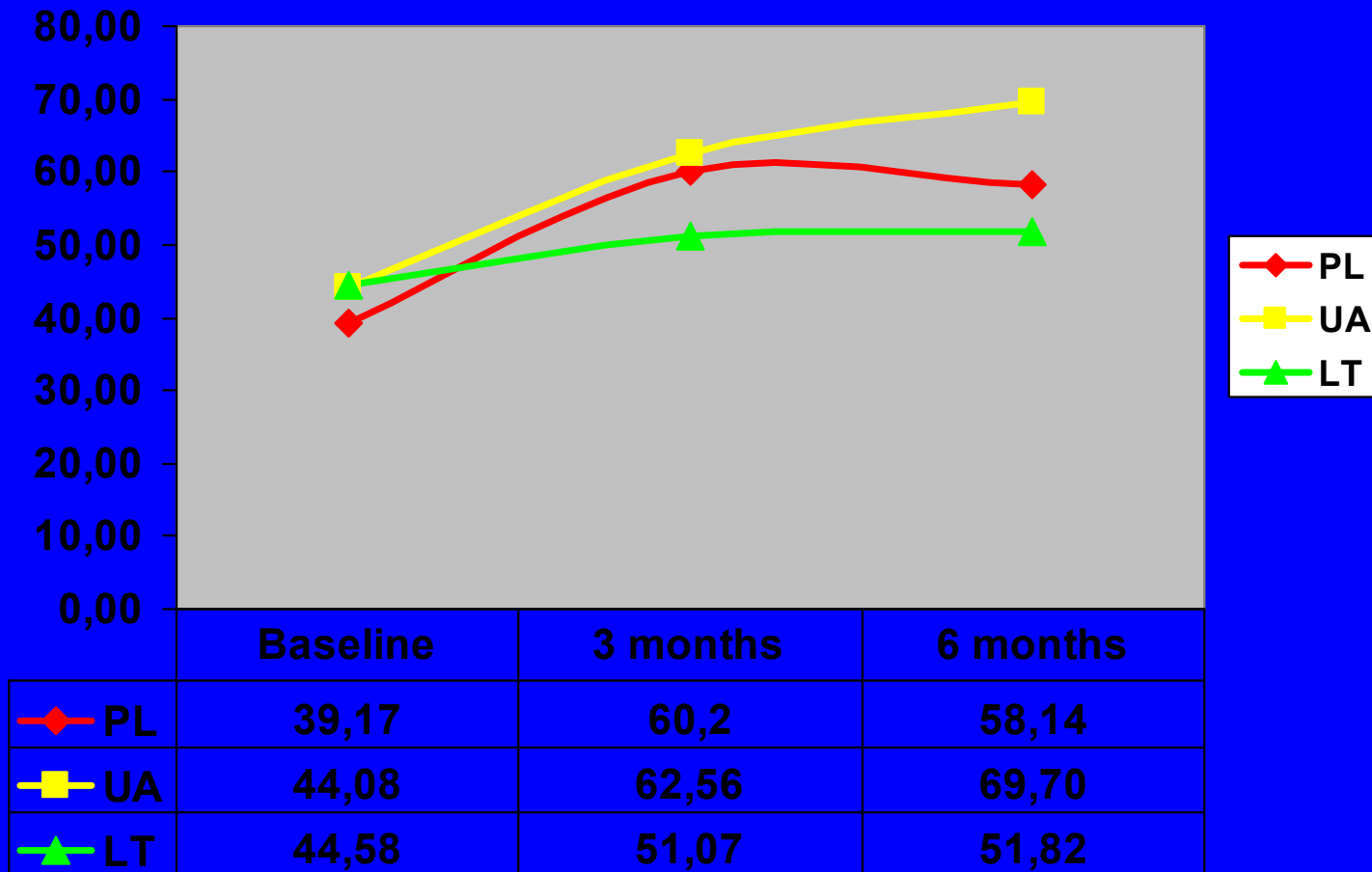
Quality of life: WHOQOL-bref



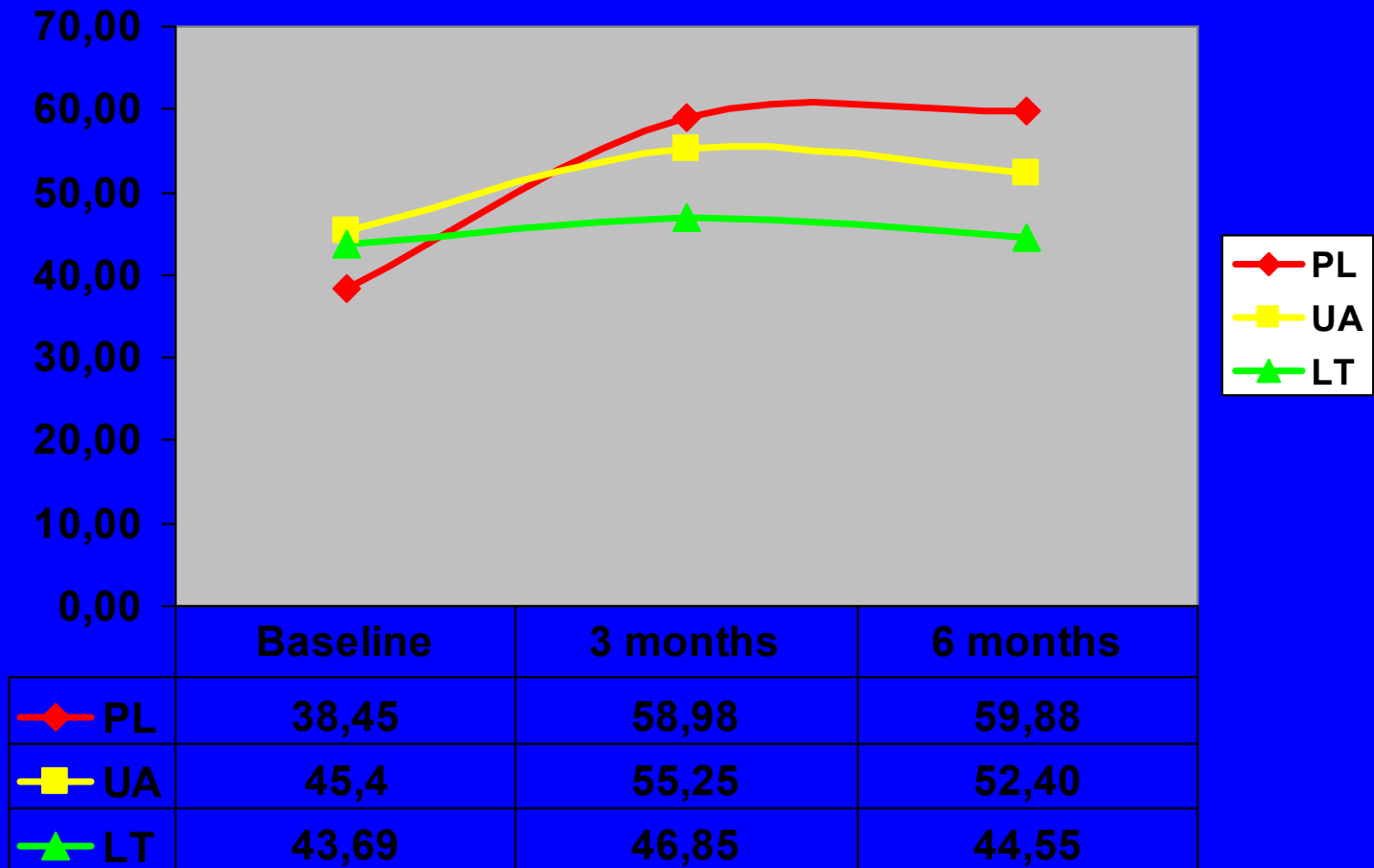
Quality of Life – Physical Domain (WHOQOL-BREF)



Quality of Life – Psychological Domain



Quality of Life – Social Domain



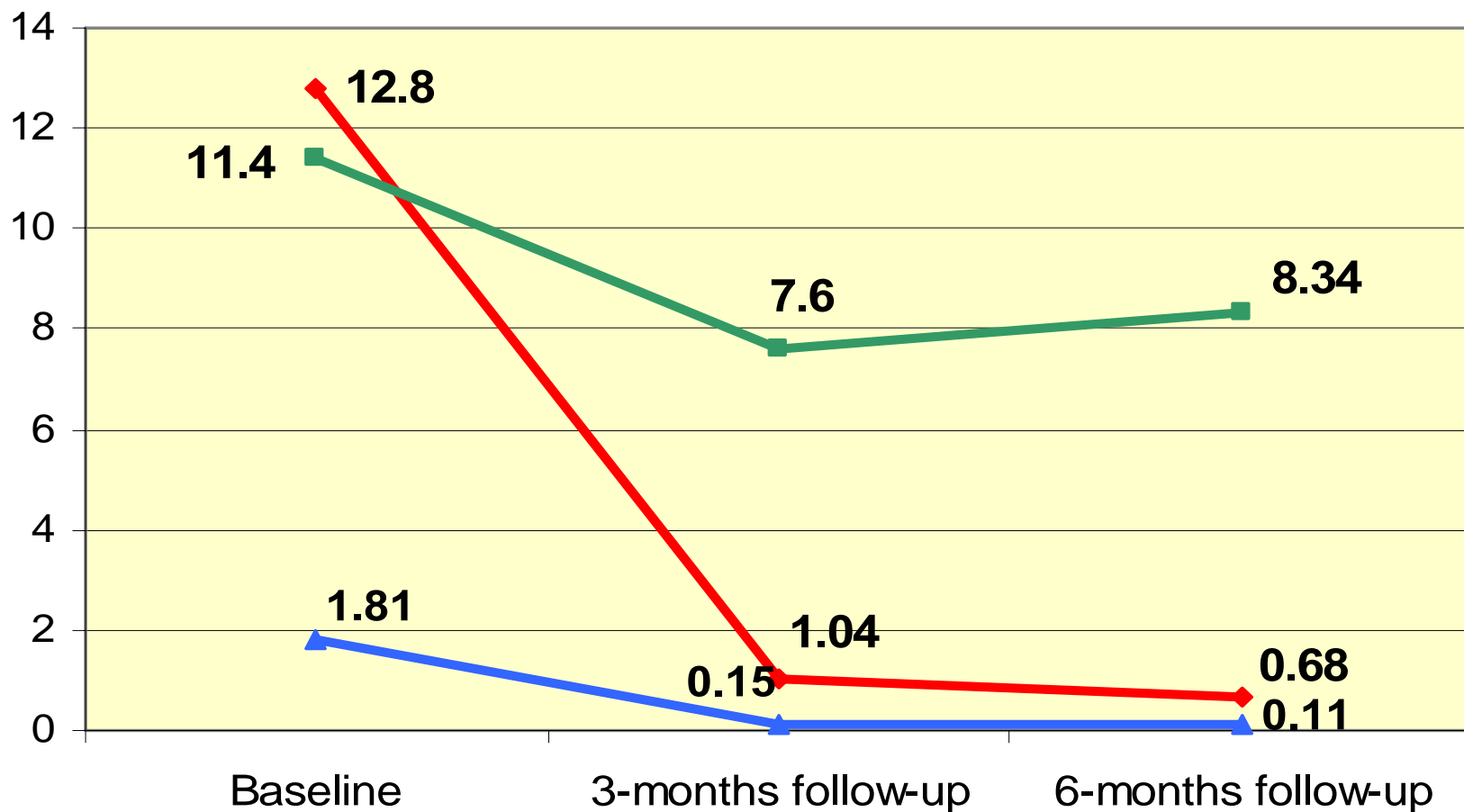
Blood Borne Virus Risk Behaviour

BBV-Traq *

Mean \pm StD (Range) BBV-Traq Subscale score	Baseline	3 months	6 months
1. Injecting practices [max score = 100]	12.8 \pm 14.5 (59 - 0)	1.04 \pm 5.8 (42 - 0)	0.68 \pm 4.9 (36 - 0)
2. Sexual practices [max score = 40]	11.4 \pm 9.5 (36 - 0)	7.6 \pm 7.9 (27 - 0)	8.34 \pm 7.4 (27 - 0)
3. Skin penetration [max score = 30]	1.81 \pm 2.5 (8 - 0)	0.15 \pm 0.63 (3 - 0)	0.11 \pm 0.47 (3 - 0)

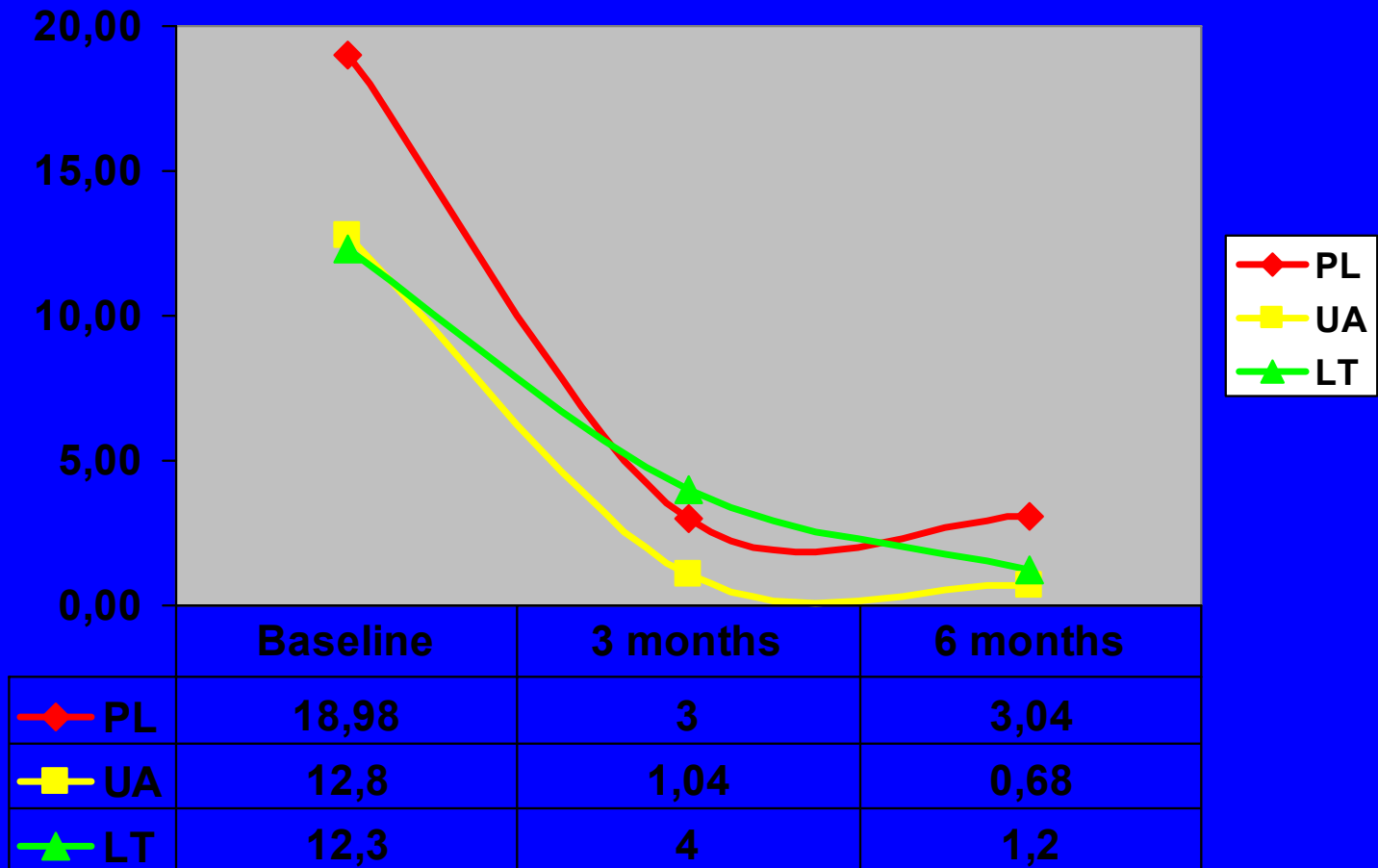
* Blood Born Virus Transmission Assessment Questionnaire

Blood Borne Virus Risk Behavior (BBV-Traq)



- ◆ Injecting practices [max score = 100]
- Sexual practices [max score = 40]
- ▲ Skin penetration [max score = 30]

Blood Borne Virus Risk Behavior – Injecting Practices (BBV-TRAQ)



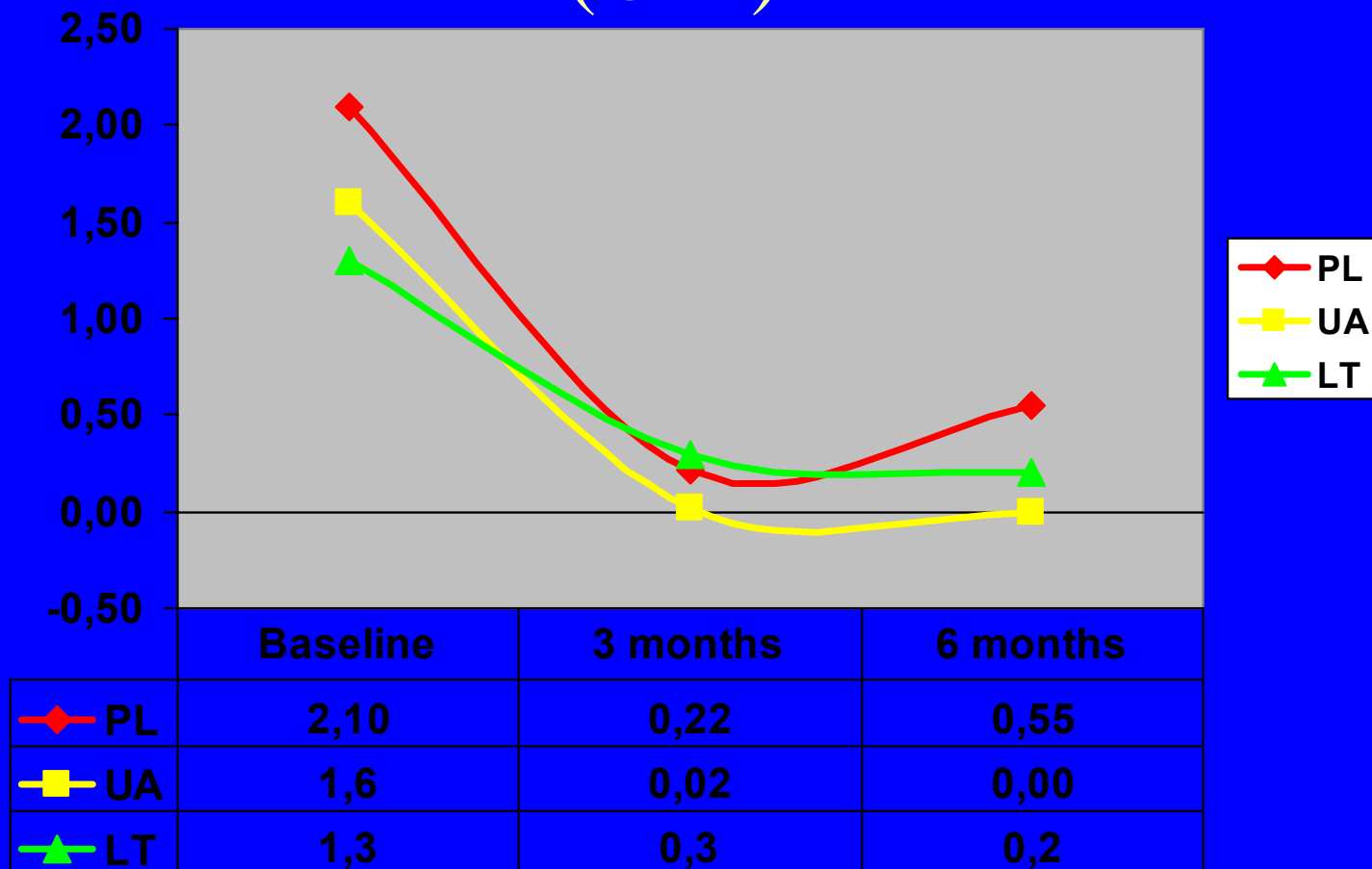
Criminal and Employment Activity

	Baseline	3 months	6 months
Self reported criminal involvement *	1.6±2	0.02±0.134	0±0
Employment Status [% employed]	44.7%	13.6%	53.8%

* OTI= Opiate Treatment Index- section two [Max score = 16].

Community /Social benefits

Self reported criminal involvement (OTI)



Programme Performance

	Baseline	3 months	6 months
Treatment retention (n (%)) *	76/100	54/71	50/66
Mean buprenorphine dose	13	7	5.45

* Refers to those still receiving maintenance treatment

Order of MoH # 161 of April 13, 2005

To start SMT implementation for opioid addicts with co-morbid HIV/AIDS in following treatment organizations:...

To use for this purpose buprenorphine (Addnok) which will be provided as humanitarian aid by International Charity Organization International HIV/AIDS Alliance in Ukraine / GFATM

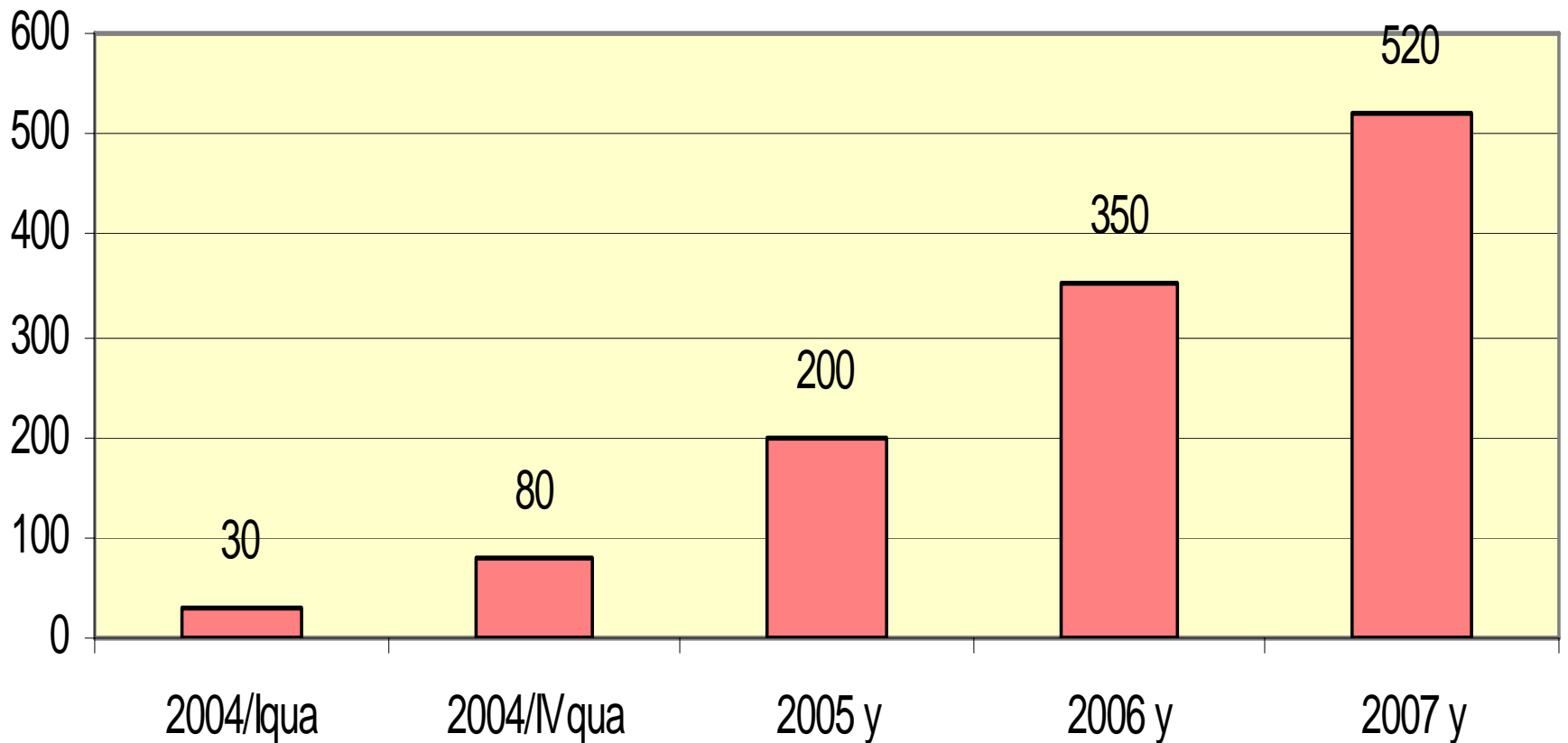
To monitor the treatment and find best models for spreading this method to all regions of Ukraine

‘The HIV/AIDS Alliance in Ukraine’ (GF-Funding) Project /2005-06/

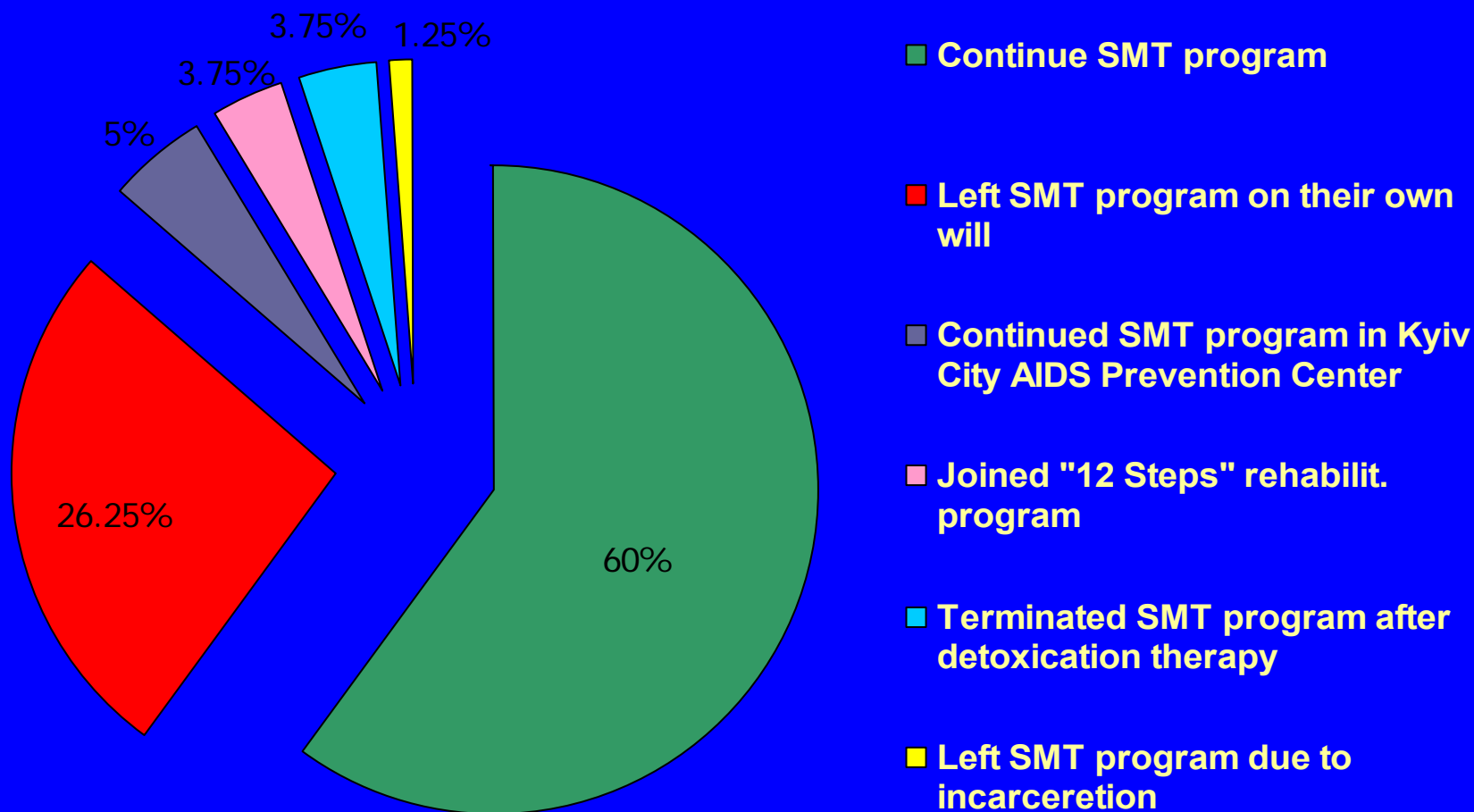
Pilot Sites:

- Kyiv – 2 sites; Donetsk, Dnipropetrovsk, Odesa, Simpheropol, Mykolayiv, Vinnitsa, Poltava, Kherson
- Start of BMT – October 2005
- Purpose: to broad access to ARV for HIV+ IDUs
- Total number of patients > 200 persons

Development of SMT Programs in Ukraine, 2003 - 2007 yy.



Substitution maintenance therapy with ADDNOK medication in Kyiv on the basis of KCNCH “Sociotherapy” (Adherence to SMT program)



National Project

“Overcoming HIV/AIDS Epidemic in Ukraine“ financing GFATM – The HIV/AIDS Alliance in Ukraine

	TOTAL	%
Number of clients (May 28, 07)	522	100
Male / Female	394/128	75/25
Mean (Years) Age / Drug Use	33,7/13,4	
Number HIV+	328	63
Number HVB/HVC	327	63
Number with HAART	105	20
Number prepared for HAAPT	66	13
Average dose of Buprenorphine, mg	10,2	
min/max dose, mg	2.0/20	
Number of drop outs in 6 months	217	29,4
Retention Rate		~70

Monitoring and Evaluation of the pilot phase

- HIV+ and HIV- IDUs
- N – 200 clients in 6 sites sites
- Instruments:
 1. For monitoring: Eligibility checklist, Patient recruitment table, Staffing table /SASQ (The Staff attitude and satisfaction questionnaire); Focus groups
 2. For evaluation: ASI-5 - Addiction Severity Index, 5 th edition (computerized version), BBV-TRAQ questionnaire (Blood borne virus transmission risk assessment questionnaire) (With baseline and 6 month follow-up data)

Demographics

Patients in the study (n)	200
Sex (% male)	154 (77%)
Age (mean)	35
Full years of education (mean)	11
The most common opioid used	Poppy straw
(%) HIV sero-positive	40%
(%) HCV sero-positive	65%

Drug use - Lifetime (ASI – Lite)

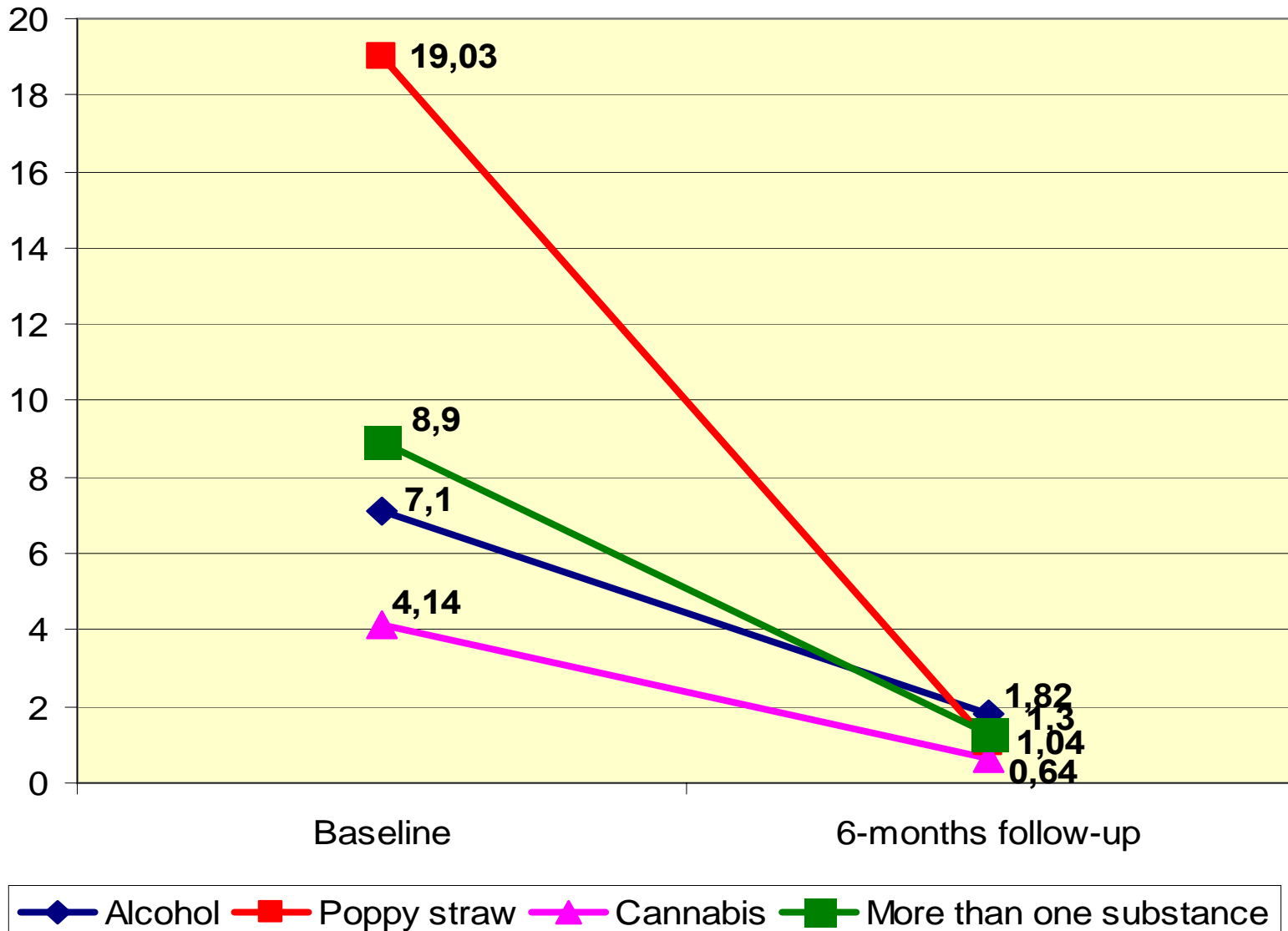
Substance	Mean number of Years
Alcohol	5,5
Heroin	0,63
Other opiates / analgetics	13,5
Barbiturates	1,42
Sedatives / tranquilizers	2,6
Cannabis	6,5
Amphetaqmines	0,3

Drug use – Previous 30 days (ASI – Lite)

Substance	Mean # of days (last 30) BASELINE	Mean # of days (last 30) 6-months FOLLOW-UP*
Alcohol	7,1	1,82
Heroin	0,08	0
Other opiates / analgetics	19,03	1,04
Barbiturates	3	0,7
Sedatives / tranquilizers	5,3	0,92
Cannabis	4,14	0,64
Amphetaqmines	0,25	0,1
More than one substance per day	8,9	1,3

* *Preliminary data*

Drug use – Previous 30 days (ASI – Lite)

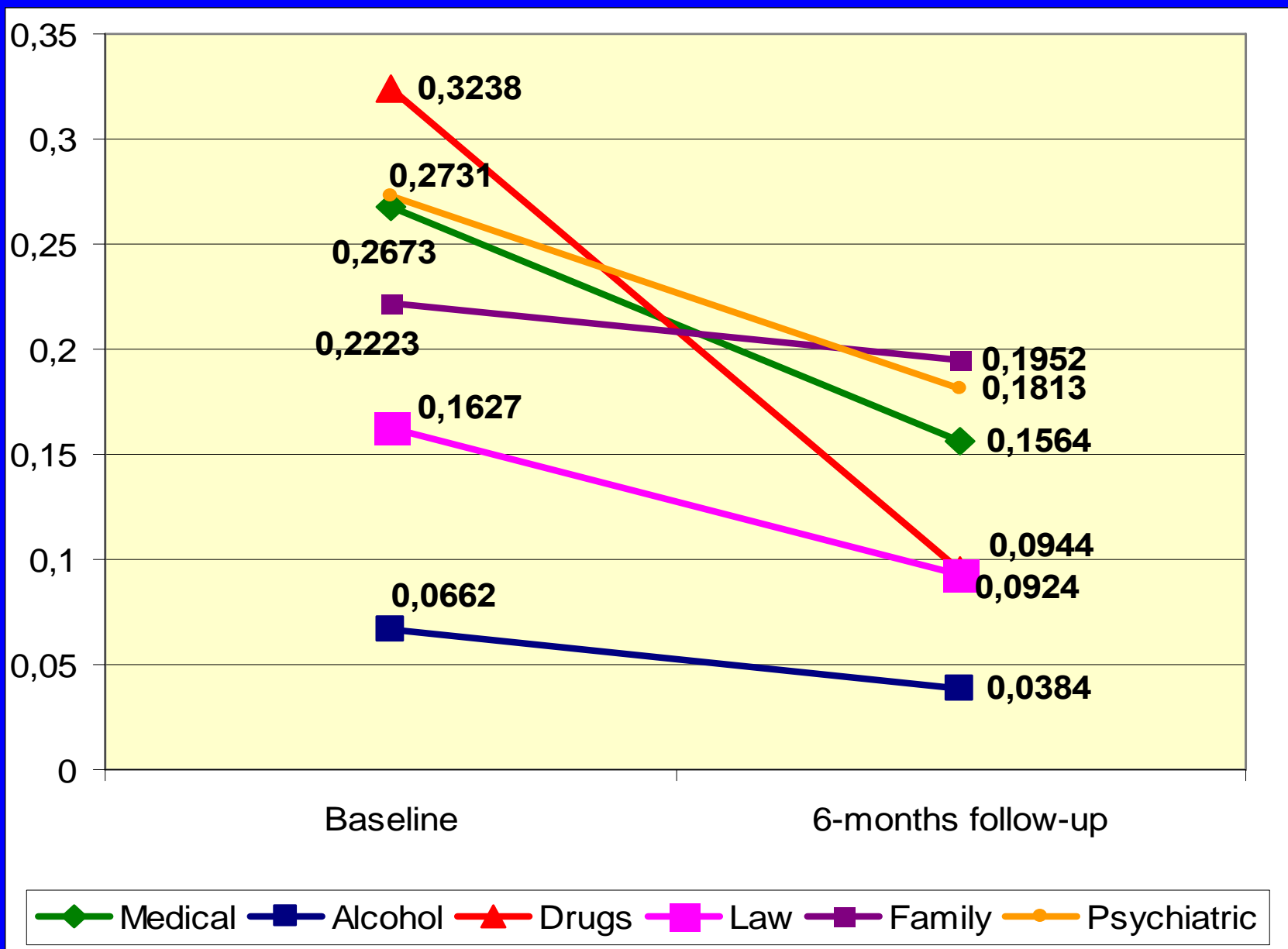


Addiction severity index - 5

ASI Domain	Mean (Baseline)	Mean (6-months follow-up)*	p-value
Medical	0,2673	0,1564	<0,001
Social status	0,7456	0,6983	0,37
Alcohol	0,0662	0,0384	0,14
Drugs	0,3238	0,0944	<0,001
Law	0,1627	0,0924	<0,001
Family	0,2223	0,1952	0,29
Psychiatric	0,2731	0,1813	<0,001

* *Preliminary data*

Addiction severity index - 5

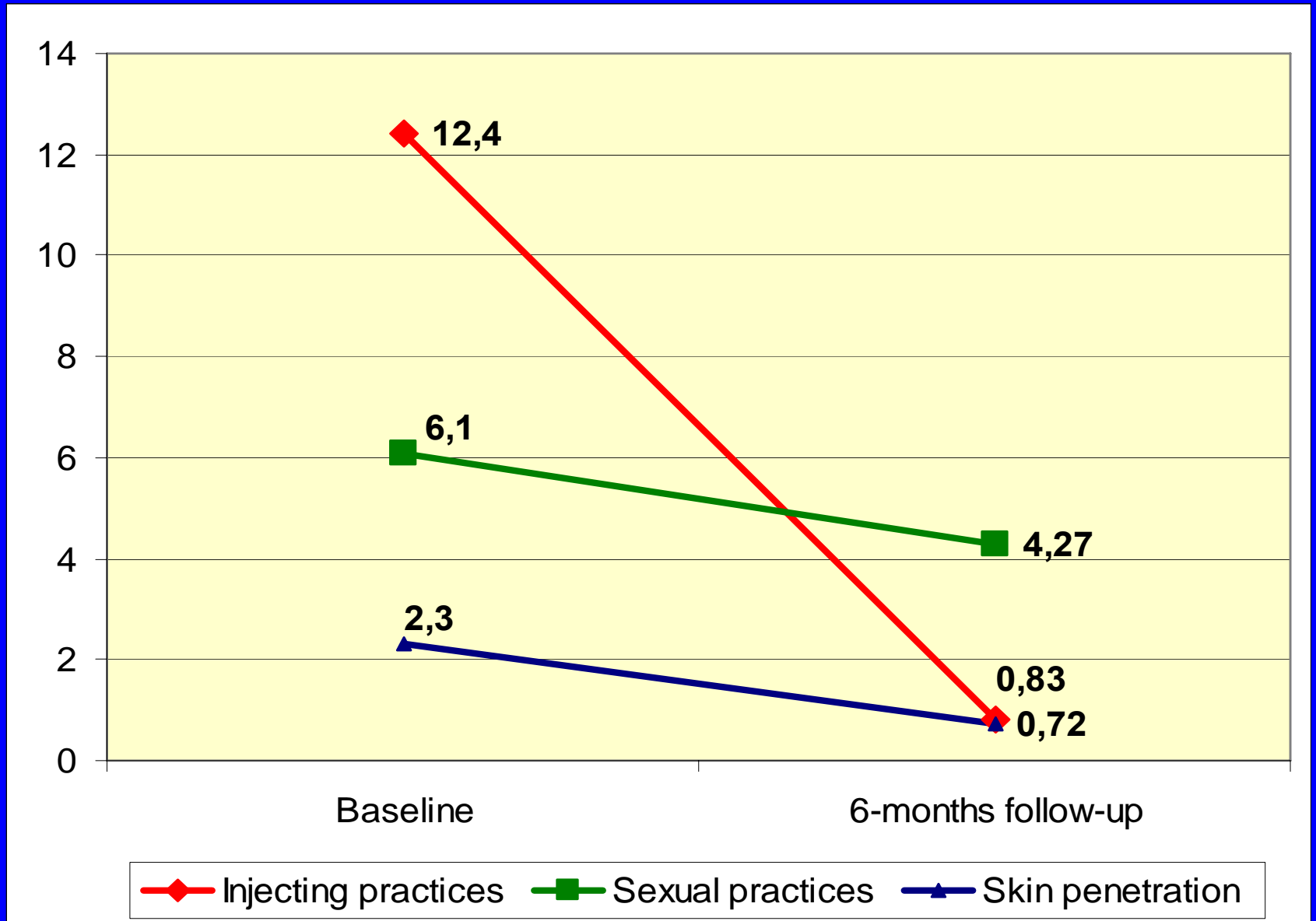


Blood Borne Virus Risk Behavior (BBV-Traq)

Subscale	Mean (Baseline)	Mean (6-months follow-up)*	p-value
1. Injecting practices [max score = 100]	12,4	0,83	<0,001
2. Sexual practices [max score = 40]	6,1	4,27	<0,05
3. Skin penetration [max score = 40]	2,3	0,72	<0,001

* *Preliminary data*

Blood Borne Virus Risk Behavior (BBV-Traq)



Buprenorphine in tablets

- **2004y** - **36 000tbls = ~ \$50 000**
- **2005y** - **96 000tbls = ~\$125 000**
- **2006y** - **432 000tbls = ~\$475 000**

Cost of Buprenorphine (Addnok)

cost per 2 mg tablet	\$1.177
logistics cost per tablet	\$0.243
Total delivered cost per 2mg tablet	\$1.42
Daily cost per patient	
8mg	\$5.68
12mg	\$8.52
16mg	\$11.36
Monthly cost per patient	
8mg	\$170.40
12mg	\$255.60
16mg	\$340.80

Total expenditure on SMT development in Ukraine (per patient data)

- 197 patients at the end of January 2006 (project duration to date - 4 months)
- Substance cost – \$42 000.
- Cost of infrastructure development projects – \$266 000
- Total expenditures – \$308 000
- **Total expends per patient a month – \$390.**

Conclusions

- **Buprenorphine (Addnok) is effective for SMT: retention in Tx; reduction of opioids use; health status & quality of life improvement; reduction of risky behavior; decrease of criminal involvement.**
- **In phase of stabilization an effective dose of buprenorphine is ~ 8-10 mg/day.**
- **Ukrainian data are similar to Poland, Lithuania etc**
- **Political context is still ambivalent and not supportive.**
- **Public health decision-makers still are not active in terms of development of SMT in Ukraine and influencing HIV-epidemic.**
- **The country needs a new strategy and practice regarding SMT to promptly respond on the epidemic challenges. Firstly to broad access to SMT providing methadone ST.**

Thank you for your attention!