

2001-2005 Report

Trends and Observations on the Collection, Testing and Use of Blood and Blood Components in Europe

European Committee (Partial Agreement)
on Blood Transfusion (CD-P-TS)

Give
blood



Trends and Observations on the Collection, Testing and Use of Blood and Blood Components in Europe

2001-2005 Report

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Director of the Publication: Dr S. Keitel

Page layout and cover: EDQM

Prepared for:

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SUMMARY

The work presented here is an attempt to obtain information on trends in the collection, testing and use of blood and blood components in Europe. The basis for the analysis is data provided annually since 2001 to the Council of Europe by its Member States (MS). As of 2004, data collection and analysis has been performed under the aegis of the European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS), a Steering Committee of the Council of Europe (CoE) supervising activities in the field of blood transfusion within the framework of the European Directorate for the Quality of Medicines and HealthCare (EDQM)¹.

CD-P-TS strongly supported this first attempt to analyse trends in Europe, based on data provided during the reporting period 2001 to 2005 during which the percent of responding countries was on average 72%.

Data from countries having provided four or more annual observations were analysed for trend using Mann Kendall or parametric test. Due to the stability of the proportion of responding countries, which facilitated robust statistical analysis, a number of observations could be made, despite the relatively short reporting period.

No trends in blood supply, platelet usage or amount of plasma for fractionation collected were observed, suggesting that these parameters remained stable during the reporting period. An increase in the use of Red Blood Cells (RBC) and notably in the use of irradiated or leucocyte depleted RBC, a small increase in Fresh Frozen Plasma (FFP) units used and a decrease in the use of Whole Blood (WB) and autologous blood use were observed during the reporting period. Whilst screening regimens for blood donors or blood donations were not substantially changed, detection of Hepatitis B virus (HBV) and Hepatitis C (HCV) virus infections amongst repeat and first time donors, respectively, appeared to decrease. Also, the implementation of Quality Assurance (QA) systems appeared to be a general trend in Europe over the period 2001-2005.

On the basis of these findings it has been decided to pursue annual data collection and to perform a new trend analysis over an extended period of time to facilitate estimation of the analysis to the MS which joined CoE after 2001.

Acknowledgements

The CoE and the authors are grateful to all colleagues and experts in MS who collated data at a national level and provided it for inclusion in this report, and especially to Prof Olof Akerblom for reviewing the initial versions of the questionnaire.

Data collection and analysis and preparation of this manuscript was coordinated by Dr Marie-Emmanuelle Behr-Gross (Scientific officer, EDQM) supported by Ms Alison Harle (secretarial assistant, EDQM) and by Ms Isabelle Vernay and Mr John O'Brien (editorial assistants, EDQM).

1. EDQM is a Directorate of the Council of Europe, created in 1964 on the legal basis of the Convention on the Elaboration of a European Pharmacopoeia. 36 Member States, the European Union and 23 observers co-operate within this framework.

LIST OF ABBREVIATIONS

CD-P-TS	European Committee (Partial Agreement) on Blood Transfusion
CI	Confidence Intervals
CoE	Council of Europe
EC	European Commission
EDQM	European Directorate for the Quality of Medicines and HealthCare
EMA	European Medicines Agency
EU	European Union
FFP	Fresh Frozen Plasma
HBc	Hepatitis B core antigen
HBsAg	Hepatitis B surface Antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HTLV	Human T cell Lymphotropic Virus
ISBT	International Society for Blood Transfusion
IU	International Unit
L	Litres
MS	Member States of the Council of Europe
NAT	Nucleic Acid Amplification Techniques
Ph. Eur.	European Pharmacopoeia
QA	Quality Assurance
RBC	Red Blood Cells
SP-GS	Committee of Experts on Quality Assurance in Blood Transfusion Services
SP-HM	Committee of Experts on Blood Transfusion
WB	Whole Blood
WHO	World Health Organisation

1. INTRODUCTION

The Council of Europe (CoE) has since 1989 a tradition of collating data on the collection, testing and use of blood in its Member States (MS). Data were supplied by MS in response to a questionnaire requesting detailed information on donors, collections, testing, distribution and quality aspects of blood and blood components. Reports which have assessed the blood supply in the MS in 1989, 1991, 1993, 1995, and 1997 were published. As of 2001, a new questionnaire has been designed by SP-GS experts and the SP-HM bureau focusing on data from blood establishments. It was felt that even though hospital data would have been very much of interest, these would be much more difficult to obtain systematically. The 2001 questionnaire stems from discussions that led to European Union (EU) *Directive 2002/98/EC*, which as a result of the *Treaty of Amsterdam* also primarily focuses on regulating the “producers” part of the blood transfusion chain. As opposed to the 1997 survey (Rejman *et al.*, 2000), since 2001 EU member states were included in the survey. As in 2001 a new systematic approach and new definitions were developed, and a qualitative evaluation report on the 2001 Questionnaire with recommendations for improvement of the process was prepared and reported to SP-HM in 2003. Improvements and amendments have been included in the questionnaire following formal approval by the SP-HM bureau. As the new 2001 format could have generated initial difficulties in data retrieval, it was expected that the quality of the survey would improve through annual repetition. In fact, the consistency of the data during the last 5 years indicates that this may have been the case. If already established, existing definitions were used from regulatory documents of the CoE (*Guide to the preparation, use and quality assurance of blood and blood components*) and the EU (*Council Recommendation 98/463/EC* and *Directive 2002/98/EC*). Some definitions were established in the field. Infectious disease definitions were elaborated during an International Society for Blood Transfusion (ISBT) Working Party on Infectious Diseases in 1996, and later were adopted by the European Medicines Agency (EMA) (within the framework of the *Guideline on epidemiological data on blood transmissible infections, EMEA/CPMP/BWP/3794/03*). In this manner, greater convergence towards more uniform definitions and data collection within Europe could be sought. In the field, this means that data can be elicited consistently from blood bank automation systems without having to adapt different computer queries for different surveys. It is to be welcomed that World Health Organisation (WHO) Europe collaborated and also subscribed to the CoE questionnaire.

This report is the first attempt to observe trends in the outcome of these surveys over a 5-year period. The goal is to bring about further insight in developments in the blood transfusion chain in Europe.

2. MATERIALS AND METHODS

2.1. METHODS FOR DATA COLLECTION

For the analysis presented in this document, the CoE data of the survey on ‘The collection, testing and use of blood and blood products in Europe’ for the years 2001 through 2005 were used (See references). Comments from MS on the draft report have been incorporated, as well as changes in the data for the reporting year 2005, which had not been finalised at the time of completion of the draft report.

Data from individual tables of the original reports (2001-2005) were collected and combined into a single table for each sub-heading/characteristic. From these newly constructed tables the changes in the reported characteristics over time could be derived. A (general) trend could also potentially be found from a graphical representation of these results. Statistical tests were performed to detect both a general overall trend and a trend for each country. In some cases, outlier observations were discarded in the analysis. The outliers were selected subjectively, on the basis of the graphical representation, and are presented in the tables in a bold typeface.

2.2. METHODS FOR STATISTICAL ANALYSIS

2.2.1. Testing for a trend for a specific country

Testing for a trend can be performed using a parametric or non-parametric test statistic. For the parametric test, in contrast to the non-parametric test, a (mostly linear) relationship is presumed between time (T) and the outcome considered (Y). In addition, the residuals are presumed to follow a normal distribution. For the non-parametric test, no such assumptions are required. This test can therefore be applied more widely. The drawback is the reduced power of such non-parametric tests.

2.2.1.1. Non-parametric Mann-Kendall test for trend

Mann first suggested using the Kendall's tau significance test for association as a test for trend (Mann, 1945), by simply using one of the variables as time and the other as the actual observations at various time points. This was directly analogous to regression, where the test for significance of the correlation coefficient r is also the significance test for a simple linear regression. The Mann-Kendall test can be stated most generally as a test for situations where observed values (Y) over time (T) tend to increase or decrease (monotonic change). The hypothesis tested is the following:

$$H_0: \text{Prob}[Y_j > Y_i] = 0.5, \text{ where time } T_j > T_i.$$

$$H_1: \text{Prob}[Y_j > Y_i] \neq 0.5 \text{ (2-sided test).}$$

No assumption of normality is required, but there must be no serial correlation for the resulting p-values to be correct. Typically the test is used for a more specific purpose, namely to determine whether the central value or median changes over time. The spread of the distribution must remain constant, though not necessarily in the original units. If a monotonic transformation such

as the scale of powers is all that is required to produce constant variance, the test statistic will be identical to that for the original units.

To perform the test, Kendall's S statistic is computed from the [T,Y] data pairs. The null hypothesis of no change is rejected when S (and therefore Kendall's tau of Y versus T) is significantly different from zero. It is then concluded that there is a monotonic trend in Y observed values over time.

2.2.1.2. Parametric test for trend

Simple linear regression of Y on T can be used to test for trend. The regression equation that is estimated is:

$$Y = \beta_0 + \beta_1 \cdot T + \varepsilon$$

The null hypothesis is that the slope coefficient $\beta_1 = 0$. Regression makes stronger assumptions about the distribution of Y over time than does Mann-Kendall (e.g. a normally distributed error term). The *t* statistic on β_1 is tested to determine if it is significantly different from 0. If there is a slope, the null hypothesis is rejected and it is concluded that there is a (linear) trend in Y over time. If the model form specified in a regression equation were known to be correct (Y is linear in T) and the residuals were truly normal, then fully-parametric regression would be optimal (most powerful and lowest error variance for the slope). Of course, this can never be known in any real world situation. If the actual situation departs, even to a small extent, from these assumptions then the Mann-Kendall procedures will either perform as well or better (Hirsch *et al.*, 1991; Onoz *et al.*, 2002). Therefore, in this report only the non-parametric test for trend was used for determining trends in individual countries.

2.2.2. Testing for overall trends

To test whether there is an overall trend, the observations from various countries have to be considered conjointly. This can be done using a regression model that estimates one single parameter for trend in combination with separate offsets for each of the individual countries. Linear Mixed Models allow for a hierarchical model structure where, next to assumptions for each of the individual countries, a general regression parameter for an overall trend is also estimated. The general regression equation for Linear Mixed Models is:

$$Y = T \cdot \beta + Z \cdot \zeta + \varepsilon$$

In this regression model one single parameter for trend (β) is estimated in combination with separate offsets (ζ) for each of the individual countries (Z). Here, the *t* statistic can also be used to test whether the regression parameter for overall trend is significantly different from zero. Alternatively, the significance of the regression parameter can be tested using a likelihood ratio test by comparing the likelihood of the regression model against the model excluding the regression parameter for trend. The parameter for overall trend can be seen as the average slope of the individual linear regression lines fitted to each of the individual countries. The test for trend can be performed in different ways: the observations can either be weighted in accordance to the population size of the country or weighted equally, implying that there is one observation per country. It was decided to perform a trend analysis on the data entries as presented in the tables. In this way the 'trend' reflects a tendency amongst MS rather than a tendency within the overall population. Only data from countries that have provided three or more data points are included in the analysis for overall trend. Data points that were considered outliers are excluded from the analysis.

3. RESULTS

3.1. INTRODUCTION

In the following chapters a summary is made for each of the tables from the individual annual CoE publications. This summary consists of a table with the data that was reported in every reporting year, a graph presenting the data graphically, and a description of observations to be made.

In each table the responses to a particular question in the questionnaire of a reporting year are given. Where data is provided that is considered an outlier, this number is printed in a bold typeface. These numbers are not used in the analysis for determining an overall trend.

The order in which the countries are presented in the table is, firstly, in descending order of the number of years of reported data and, secondly, in alphabetical order.

The right hand most column of the data tables, with the header 'Trend', indicates the p-value for the Mann-Kendall test for trend. A p-value of 5% means that there is a 5% probability that, given that there is no trend (i.e. the null hypothesis is true), a test statistic at least as extreme as the one that was actually observed would have been obtained. A test for trend is only applied to four or more observations. The p-values indicated are positive for positive trends and negative for negative trends, respectively.

In some of the graphs the y-axis is scaled logarithmically. In those cases any reported zeros in the data tables are omitted from the graph as these cannot be presented on a logarithmic scale. Conversely, in some of the (logarithmic) graphs, data points are shown that are indicated as zeros (0.00) in the tables. This is due to the fact that in the tables all numbers are limited to a maximum of two decimal places only.

3.2. NUMBER OF RESPONSES

Out of the total of 46 MS, 21 completed and submitted a questionnaire for the years 2001-2005, thus providing 5 responses. There were 6 MS with 4 responses, 5 with 3 responses, 3 with 2 responses, 9 with 1 response, and 2 MS did not respond (see Figure 1).

Table 1 shows the response per country per year. The proportion of respondents, as well as the total number of respondents and total number of MS are presented in this table.

It should be noted that two countries joined in 2002 and one joined in 2005. These countries have only had the opportunity to submit four and one response(s), respectively.

From this table it is clear that the highest response rate was observed in 2001.

As regards Liechtenstein, no data could be obtained as blood transfusion activities are run by operators acting under the responsibility of control authorities from neighbouring countries.

Similar agreements may be in place between Andorra, San Marino and their respective neighbouring countries, thus accounting for lack of reporting.

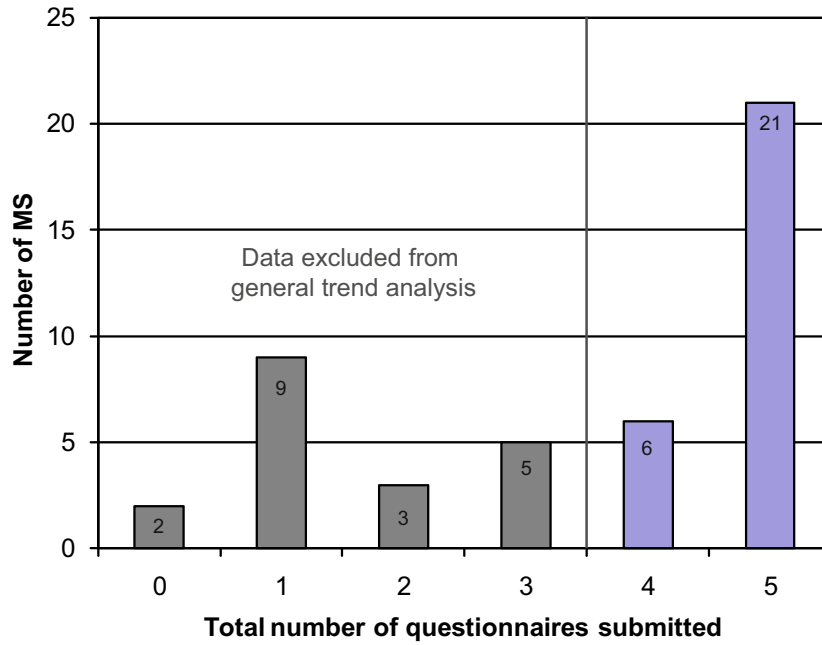


Figure 1 - Distribution of number of questionnaires submitted

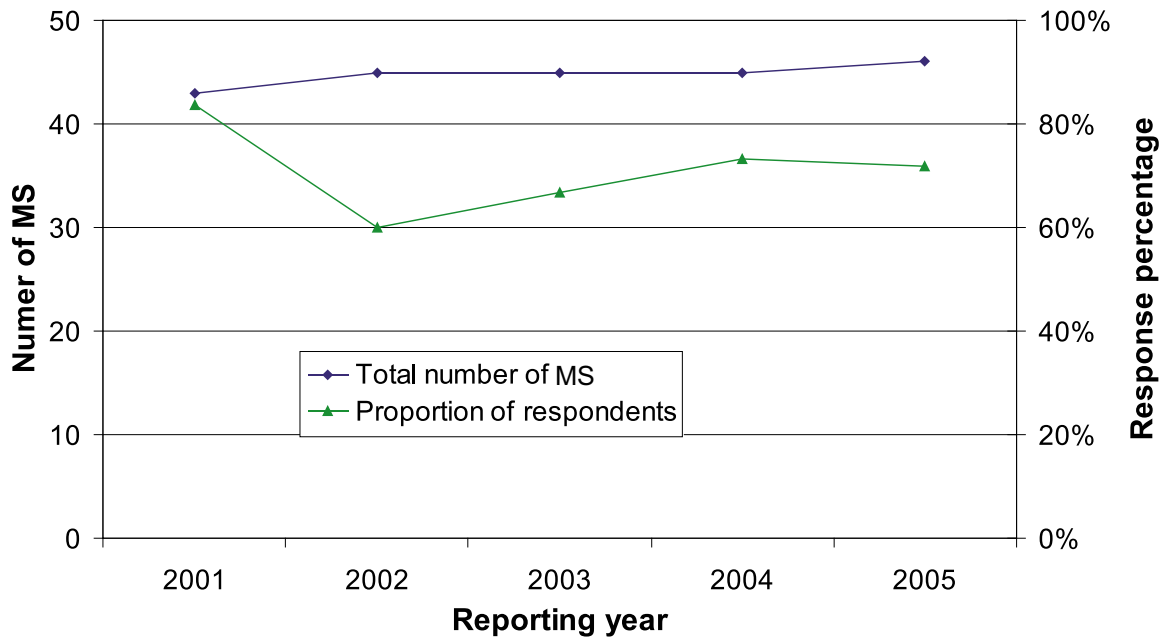


Figure 2 - Number of member states and response rate per year

Table 1 – Responses per member state per year

Country	Year					Total responses
	2001	2002	2003	2004	2005	
Belgium						5
Bulgaria						
Croatia						
Czech Republic						
Finland						
France						
Germany						
Greece						
Iceland						
Italy						
Latvia						
Luxembourg						
Netherlands						
Norway						
Poland						
Romania						
Slovak Republic						
Slovenia						
Sweden						
Switzerland						
United Kingdom						
Austria						4
Denmark						
Georgia						
Hungary						
Ireland						
Lithuania						3
Armenia						
Azerbaijan						
Bosnia / Herzegovina						2
Moldova						
Spain						1
Portugal						
Serbia						
Turkey						
Albania						
Andorra						0
Cyprus						
Estonia						
Former Yug. Rep. Macedonia						
Malta						
Montenegro						
Russian Federation						
Ukraine						
Liechtenstein						
San Marino						
Number responding	36	27	30	33	33	
Total number MS	43	45	45	45	46	
% responding	84%	60%	67%	73%	72%	

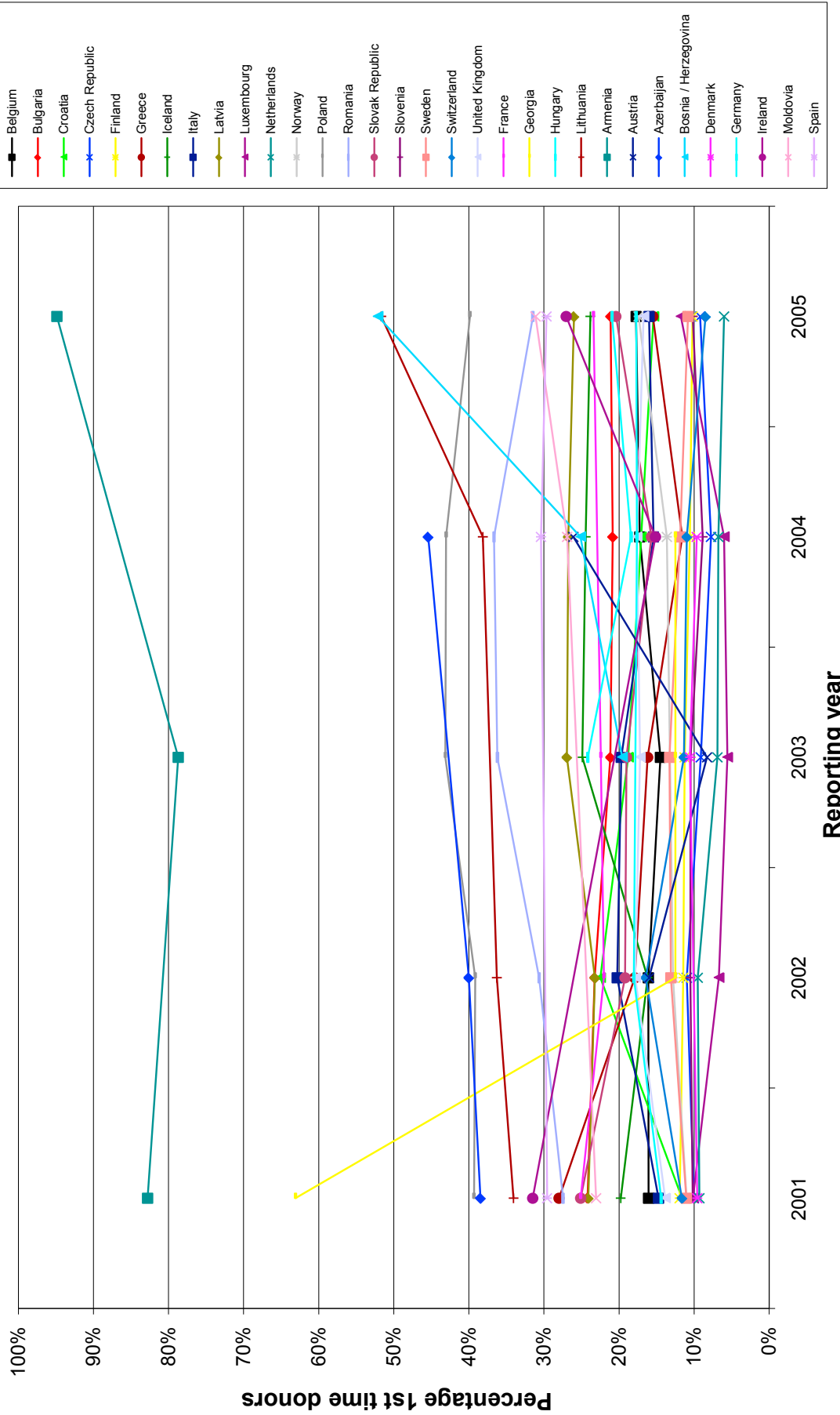
Data excluded
from general
trend analysis

Data obtained
No data obtained
Not a member state



3.3. PERCENTAGE FIRST TIME DONORS

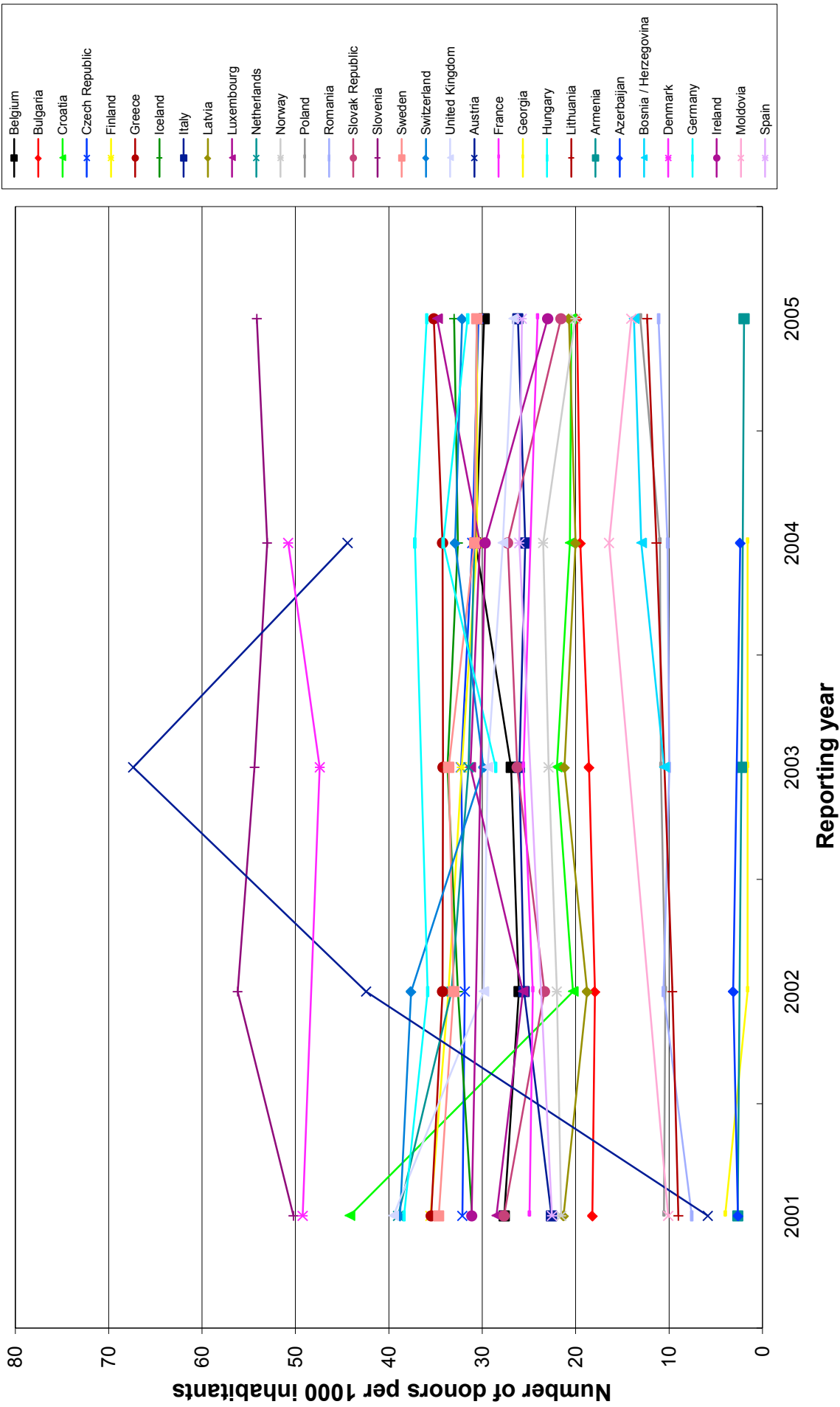
Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	16	16	14	17	18	-
Bulgaria	24	23	21	21	21	-10%
Croatia	12	22	19	17	15	-
Czech Republic	10	11	9	8	9	-
Finland	12	11	11	11	10	-5%
Greece	28	18	16	12	15	-10%
Iceland	20	16	25	24	24	-
Italy	15	20	20	15	16	-
Latvia	24	23	27	27	26	-
Luxembourg	10	7	6	6	12	-
Netherlands	9	10	7	7	6	-10%
Norway	11	13	13	14	17	5%
Poland	39	39	43	43	40	-
Romania	27	31	36	37	31	-
Slovak Republic	25	19	19	16	20	-
Slovenia	10	11	10	9	10	-
Sweden	11	13	13	12	11	-
Switzerland	12	16	11	11	8	-10%
United Kingdom	14	18	17	18	17	-
France	25	22	22		23	-
Georgia	63	13	13	13		-
Hungary	14	18		18	18	-
Lithuania	34	36		38	52	10%
Armenia	83		79		95	
Austria		16	8	26		
Azerbaijan	38	40		45		
Bosnia / Herzegovina			20	25	52	
Denmark	10		11	10		
Germany			24	18	21	
Ireland	32			15	27	
Moldova	23			27	31	
Spain	30			30	30	
Albania	75					
Andorra		6				
Estonia	31					
Former Yug. Rep. Macedonia			29			
Montenegro					34	
Portugal	29					
Russian Federation				27		
Serbia and Montenegro			40			
Ukraine			28			
Cyprus						
Liechtenstein						
Malta						
San Marino						
Turkey						



3.3: There are 7 out of the 23 countries with four or more entries that show a significant trend. Of these seven there are two upward and five downward trends (Norway(+), Lithuania(+), Bulgaria(+), Finland(-), Greece(-), Netherlands(-), Switzerland(-)). There is no statistically significant general trend.

3.4. DONORS PER 1000 INHABITANTS

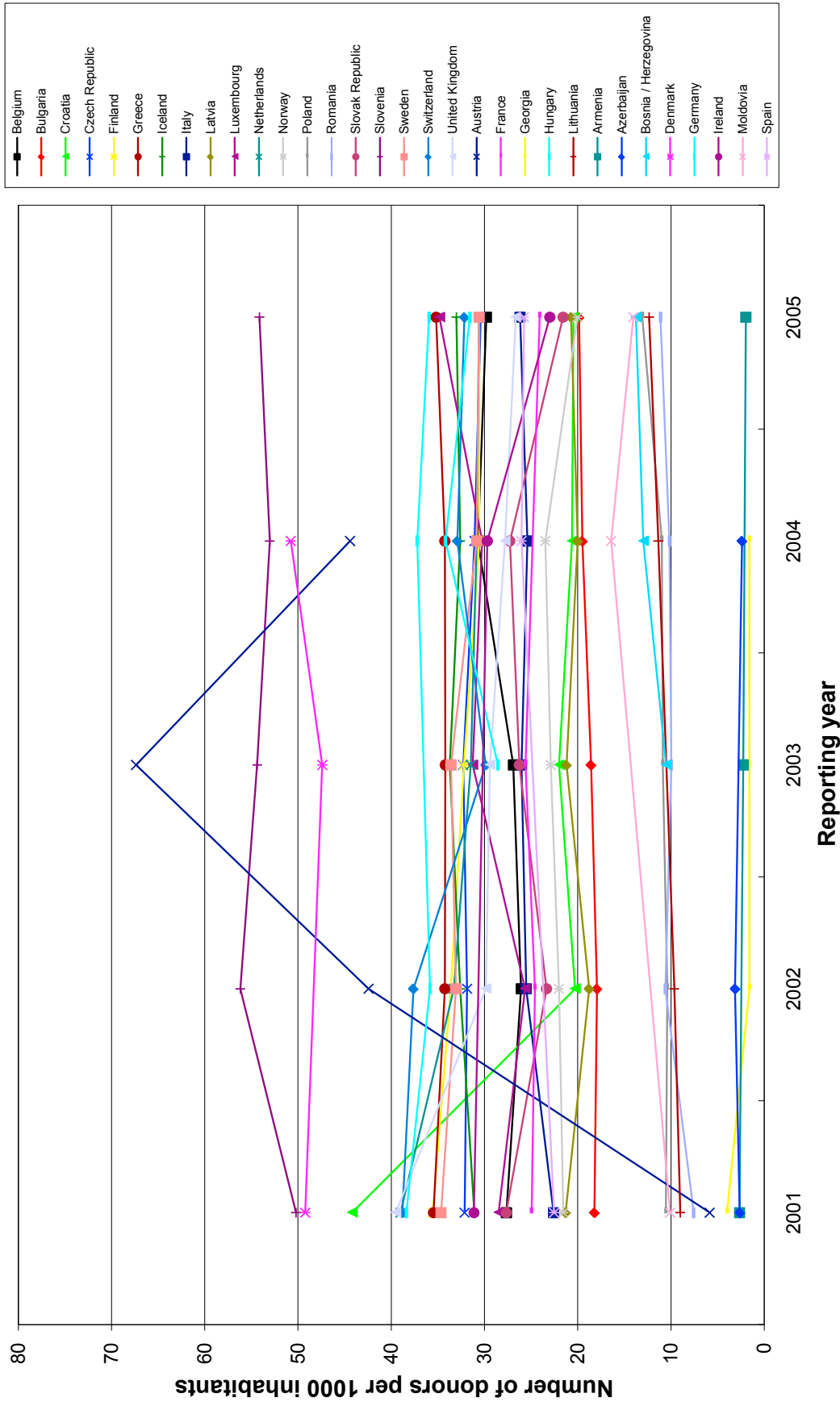
Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	28	26	27	31	30	-
Bulgaria	18	18	19	19	20	10%
Croatia	44	20	22	21	20	-
Czech Republic	32	32	32	31	30	-
Finland	36	34	32	31	31	-5%
Greece	35	34	34	34	35	-
Iceland	31	33	34	33	33	-
Italy	23	26	26	25	26	-
Latvia	21	19	21	20	21	-
Luxembourg	28	26	31	30	35	-
Netherlands	39	33	31	31	31	-5%
Norway	22	22	23	23	20	-
Poland	11	10	11	11	13	10%
Romania	8	11	10	10	11	-
Slovak Republic	28	23	26	27	22	-
Slovenia	50	56	54	53	54	-
Sweden	35	33	34	31	31	-10%
Switzerland	39	38	30	33	32	-
United Kingdom	40	30	29	28	27	-5%
Austria	6	42	67	44		-
France	25	25	26		24	-
Georgia	4	2	2	2		-
Hungary	38	36		37	36	-
Lithuania	9	10		11	12	10%
Armenia	3		2		2	
Azerbaijan	3	3		2		
Bosnia / Herzegovina			11	13	14	
Denmark	49		47	51		
Germany			29	34	32	
Ireland	31			30	23	
Moldova	10			16	14	
Spain	23			26	26	
Andorra		32				
Cyprus	33					
Estonia	21					
Former Yug. Rep. Macedonia			13			
Montenegro					0	
Portugal	11					
Russian Federation				20		
Serbia and Montenegro			24			
Turkey	16					
Ukraine			22			
Albania						
Liechtenstein						
Malta						
San Marino						



3.4: There are 7 out of the 24 countries with four or more entries that show a significant trend. Of these seven there are three upward and four downward trends (Bulgaria(+), Poland(+), Lithuania(+), Finland(-), Netherlands(-), Sweden(-), United Kingdom(-)). There is no statistically significant general trend.

3.5. WHOLE BLOOD DONATIONS PER 1000 INHABITANTS

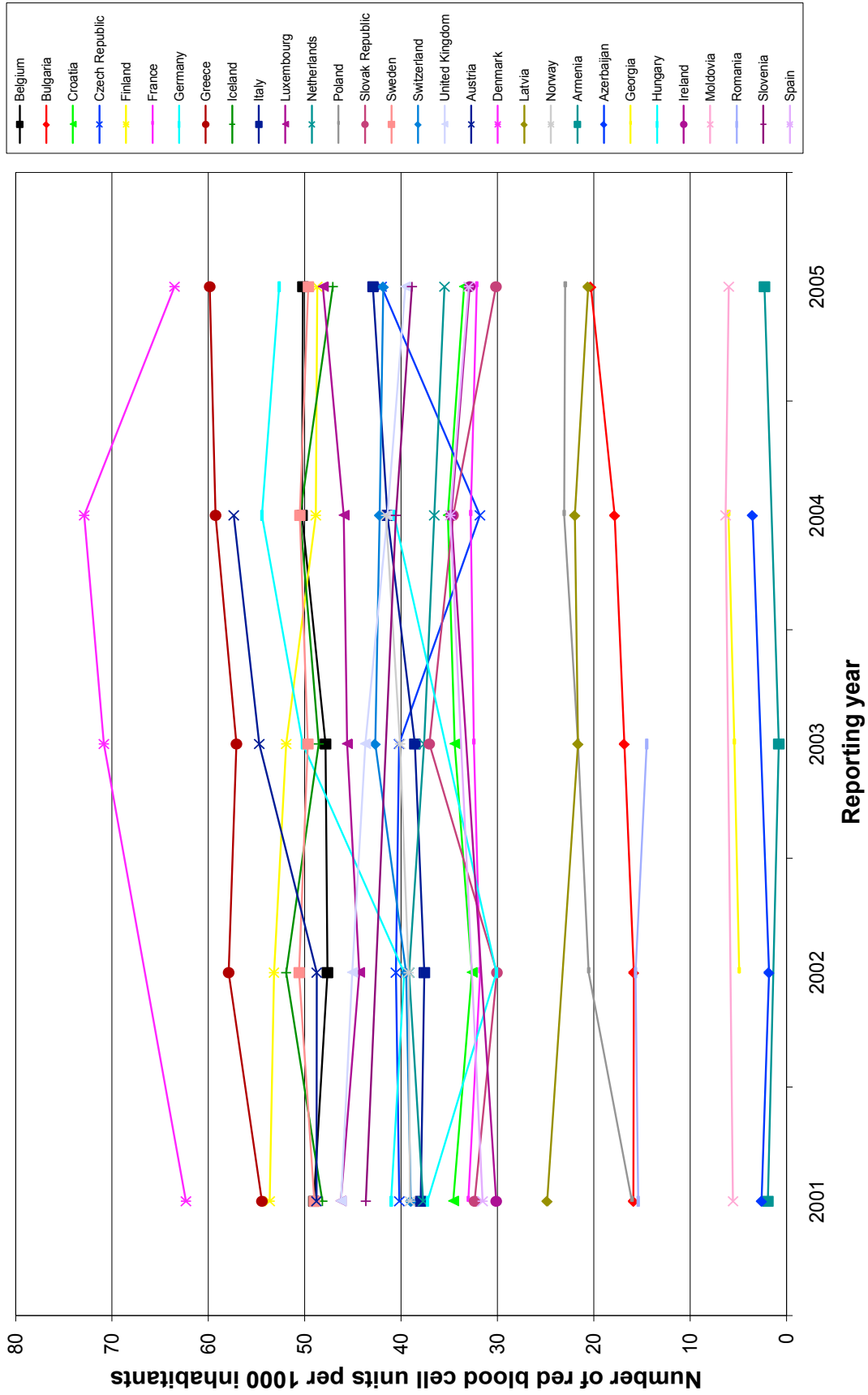
Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	53	52	50	54	54	-
Bulgaria	18	18	19	19	20	10%
Croatia	35	35	36	35	35	-
Czech Republic	40	42	42	42	41	-
Finland	60	59	57	54	52	-5%
France	35	35	37	34	34	-
Germany	55	58	56	57	56	-
Greece	54	57	57	59	59	5%
Iceland	48	54	50	51	49	-
Italy	36	38	38	40	41	5%
Latvia	25	24	25	24	23	-10%
Luxembourg	49	48	50	48	50	-
Netherlands	44	44	41	39	37	-10%
Norway	42	42	44	44	43	-
Poland	21	23	23	24	24	5%
Romania	16	16	15	17	17	-
Slovak Republic	34	32	30	26	31	-
Slovenia	45	45	43	43	43	-
Sweden	51	52	54	52	53	-
Switzerland	59	59	54	51	47	-10%
United Kingdom	50	48	47	44	42	-5%
Austria	63	56	62	61		-
Denmark	67		73	74	68	-
Georgia	4	5	5	6		-
Hungary	43	44		50	43	-
Ireland	36		37	39	37	-
Lithuania	21	22		24	26	10%
Armenia	3		2		2	
Azerbaijan	2	2		3		
Bosnia / Herzegovina			9	10	14	
Moldova	11			18	15	
Spain	36			38	36	
Portugal	12				35	
Serbia and Montenegro			21		31	
Turkey	13				17	
Andorra		12				
Cyprus	33					
Estonia	37					
Former Yug. Rep. Macedonia			24			
Malta				38		
Montenegro					0	
Russian Federation				0		
Ukraine			18			
Albania						
Liechtenstein						
San Marino						



3.5: There are 10 out of the 27 countries with four or more entries that show a significant trend. Of these ten there are five upward and five downward trends (Bulgaria(+), Greece(+), Italy(+), Poland(+), Lithuania(+), Finland(+), Latvia(-), Netherlands(-), Switzerland(-), United Kingdom(-)). There is no statistically significant general trend.

3.6. RBC PER 1000 INHABITANTS

Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	49	48	48	50	50	-
Bulgaria	16	16	17	18	20	10%
Croatia	35	33	34	35	33	-
Czech Republic	40	41	40	32	42	-
Finland	54	53	52	49	49	-5%
France	33	32	32	33	32	-
Germany	41	40	50	54	53	-
Greece	54	58	57	59	60	10%
Iceland	48	52	49	50	47	-
Italy	38	38	39	41	43	10%
Luxembourg	46	44	46	46	48	-
Netherlands	38	39	38	37	35	-10%
Poland	16	21	22	23	23	10%
Slovak Republic	32	30	37	35	30	-
Sweden	49	51	50	50	50	-
Switzerland	39	39	43	42	42	-
United Kingdom	46	45	44	41	40	-5%
Austria	49	49	55	57		-
Denmark	62		71	73	64	-
Latvia	25		22	22	21	-
Norway	39	39	40	42		10%
Armenia	2		1		2	
Azerbaijan	3	2		4		
Georgia		5	5	6		
Hungary	37	30		41		
Ireland	30			35	33	
Moldova	6			6	6	
Romania	15	16	15			
Slovenia	44			41	39	
Spain	32			35	33	
Bosnia / Herzegovina			9	9		
Lithuania	18	44				
Portugal	12				34	
Serbia and Montenegro			21		31	
Andorra		11				
Cyprus	74					
Estonia	37					
Former Yug. Rep. Macedonia			48			
Malta				38		
Turkey	12					
Ukraine			0			
Albania						
Liechtenstein						
Montenegro						
Russian Federation						
San Marino						

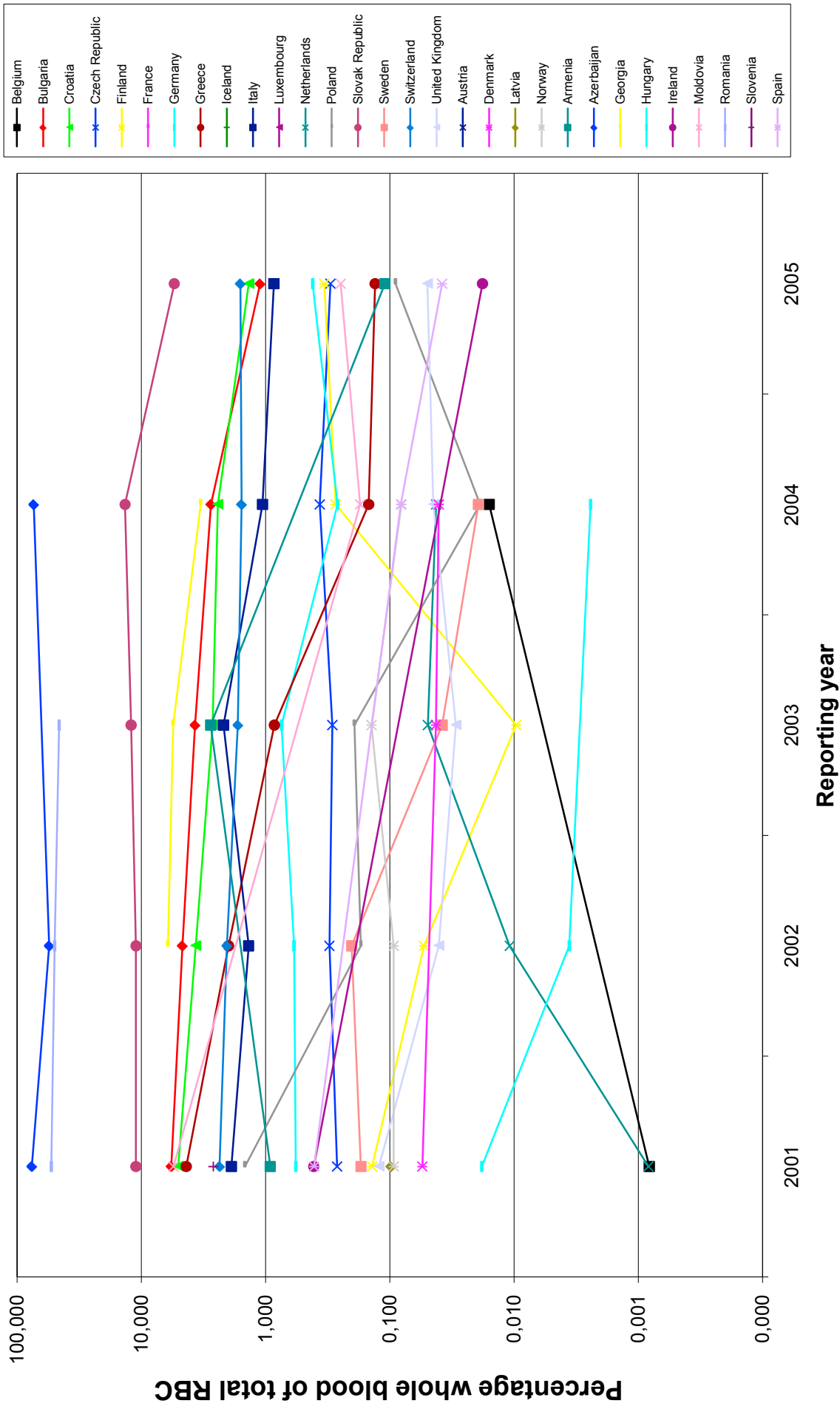


3.6: There are 8 out of the 21 countries with four or more entries that show a significant trend. Of these eight there are five upward and three downward trends (Bulgaria(+), Greece(+), Italy(+), Poland(+), Norway(+), Finland(+), Netherlands(-), United Kingdom(-)).

There is a statistically significant general increase of 0.38 red blood cell (RBC) units per 1000 inhabitants (p value of 0.02, 95% Confidence Intervals (CI) 0.05-0.71).

3.7. PERCENTAGE WHOLE BLOOD USED OUT OF TOTAL RBC

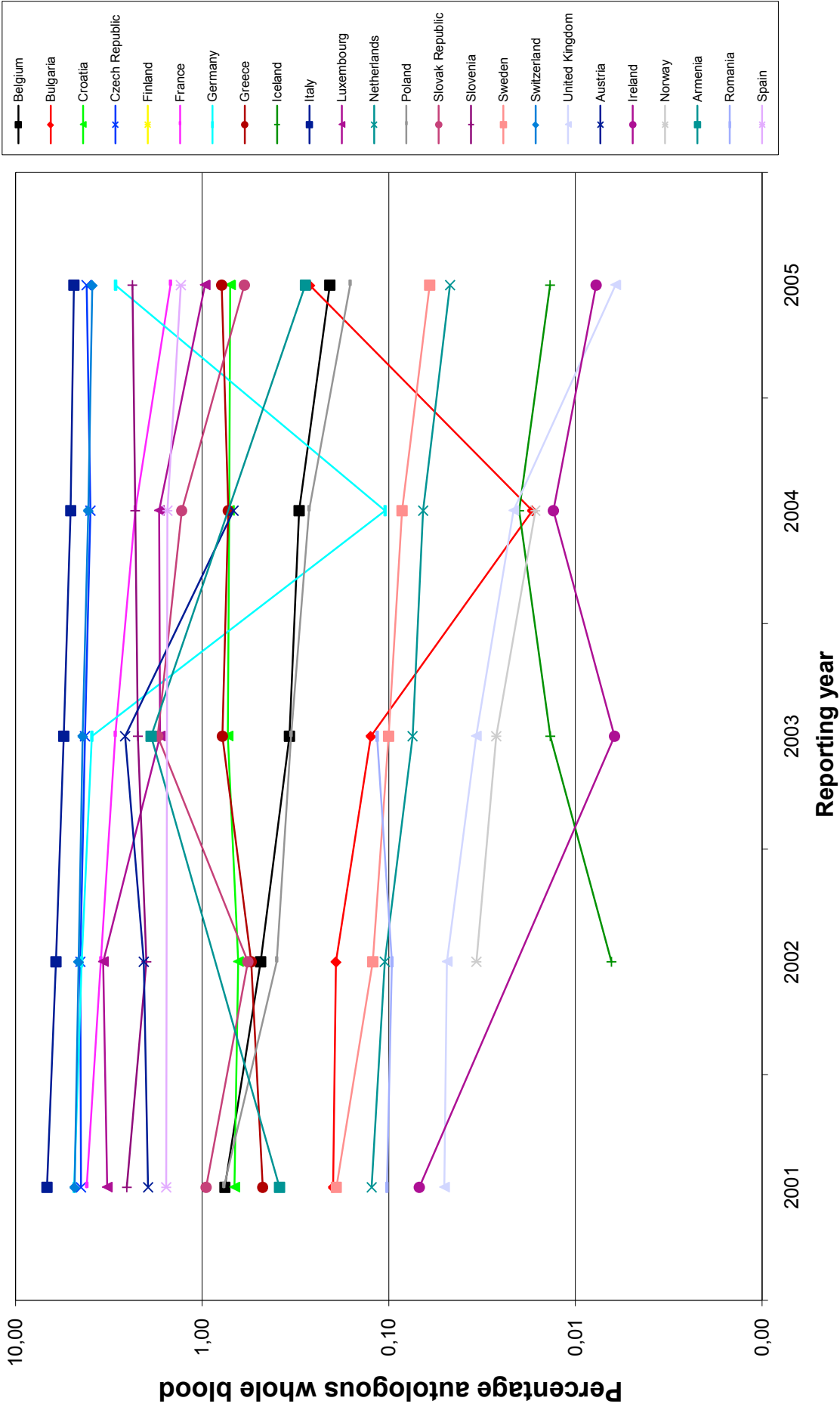
Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	0.00	0.00	0.00	0.02	0.00	-
Bulgaria	5.74	4.67	3.69	2.75	1.11	-5%
Croatia	5.05	3.66	2.67	2.43	1.36	-5%
Czech Republic	0.27	0.31	0.29	0.37	0.30	-
Finland	0.14	0.05	0.01	0.27	0.34	-
France	0.00	0.00	0.00	0.00	0.00	-
Germany	0.57	0.59	0.74	0.26	0.42	-
Greece	4.35	1.99	0.85	0.15	0.13	-5%
Iceland	0.00	0.00	0.00	0.00	0.00	-
Italy	1.89	1.37	2.18	1.06	0.86	-
Luxembourg	0.00	0.00	0.00	0.00	0.00	-
Netherlands	0.00	0.01	0.05	0.04	0.00	-
Poland	1.47	0.17	0.19	0.02	0.09	-
Slovak Republic	11.06	11.06	12.09	13.53	5.44	-
Sweden	0.17	0.20	0.04	0.02	0.00	-10%
Switzerland	2.35	2.05	1.67	1.56	1.60	-10%
United Kingdom	0.12	0.04	0.03	0.04	0.05	-
Austria	0.00	0.00	0.00	0.00		-
Denmark	0.05		0.04	0.04	0.00	-10%
Latvia	0.10		0.00	0.00	0.00	-
Norway	0.09	0.09	0.14	0.08		-
Armenia	0.92		2.76		0.11	
Azerbaijan	76.15	55.17		73.45		
Georgia		6.12	5.56	3.33		
Hungary	0.02	0.00		0.00		
Ireland	0.41			0.00	0.02	
Moldova	5.52			0.17	0.25	
Romania	53.09	49.93	45.92			
Slovenia	2.63			0.00	0.00	
Spain	0.41			0.08	0.04	
Bosnia / Herzegovina	.	.	24.36	36.90	.	
Lithuania	0.18	50.94	.	.	.	
Portugal	0.03	.	.	.	0.00	
Serbia and Montenegro	.	.	32.55	.	4.97	
Albania	20.62	
Andorra	.	0.00	.	.	.	
Cyprus	59.21	
Estonia	0.12	
Former Yug. Rep. Macedonia	.	.	51.15	.	.	
Malta	.	.	.	0.00	.	
Turkey	80.33	
Ukraine	.	.	9.48	.	.	
Liechtenstein	
Montenegro	
Russian Federation	
San Marino	



3.7: There are 6 out of the 21 countries with four or more entries that show a statistically significant trend (Bulgaria, Croatia, Greece, Sweden, Switzerland, Denmark). All of these six are downward trends. There is also a statistically significant general trend (p-value of 0.02) of 0.12 log10, which is equivalent to a relative reduction of 24% annually (95% CI 13%-34%).

3.8. PERCENTAGE AUTOLOGOUS OUT OF TOTAL WHOLE BLOOD

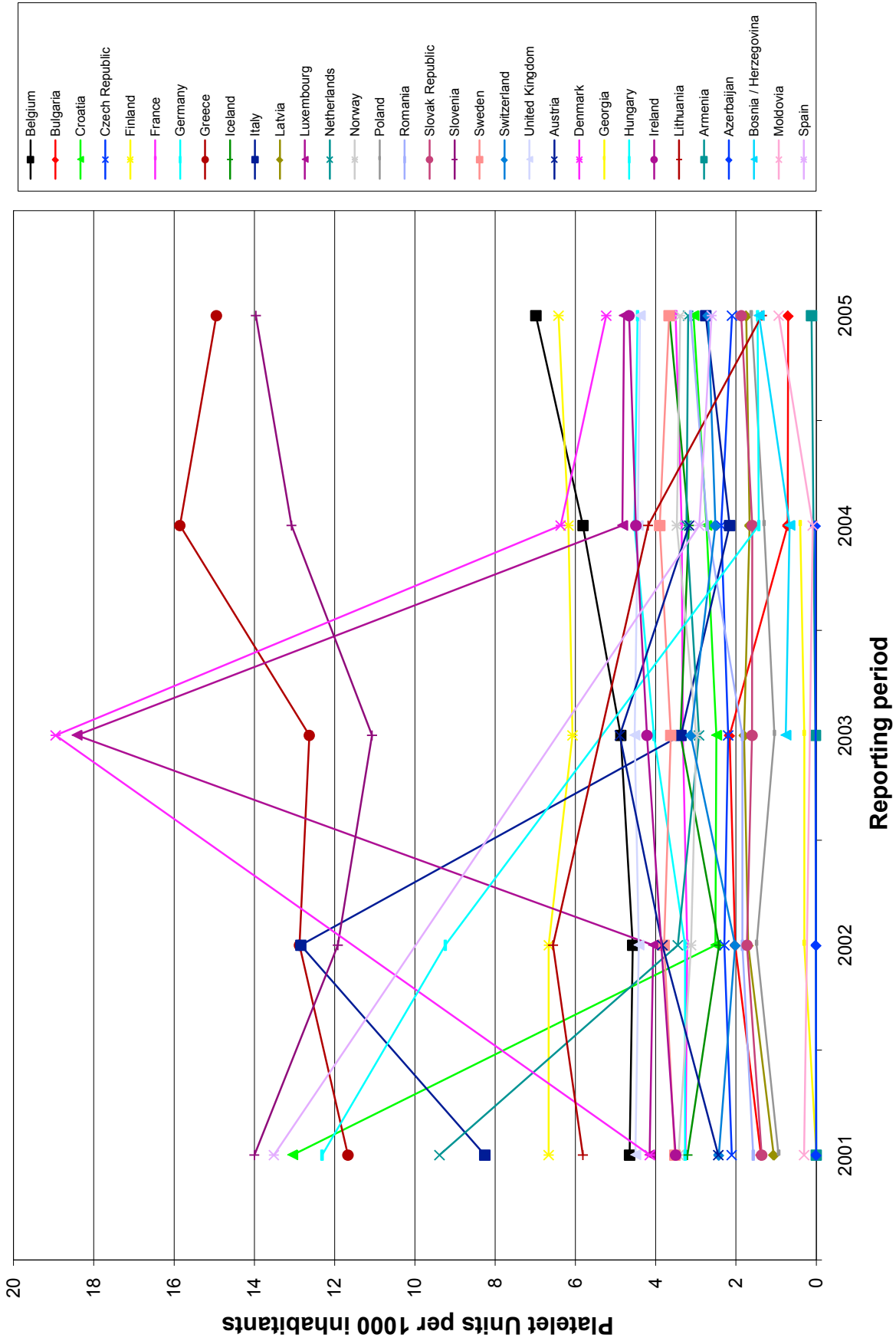
Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	0.76	0.49	0.34	0.30	0.21	-5%
Bulgaria	0.20	0.19	0.12	0.02	0.26	-
Croatia	0.67	0.64	0.73	0.72	0.71	-
Czech Republic	4.46	4.49	4.24	3.97	4.16	-
Finland	0.00	0.00	0.00	0.00	0.00	-
France	4.15	3.49	2.92	2.28	1.48	-5%
Germany	4.84	4.42	3.90	0.10	2.91	-10%
Greece	0.47	0.55	0.78	0.72	0.79	10%
Iceland	0.00	0.01	0.01	0.02	0.01	10%
Italy	6.78	6.07	5.51	5.06	4.86	-5%
Luxembourg	3.23	3.39	1.68	1.70	0.97	-
Netherlands	0.12	0.10	0.07	0.07	0.05	-5%
Poland	0.76	0.40	0.33	0.27	0.16	-5%
Slovak Republic	0.95	0.57	1.73	1.29	0.59	-
Slovenia	2.53	1.99	2.21	2.28	2.36	-
Sweden	0.19	0.12	0.10	0.08	0.06	-5%
Switzerland	4.82	4.59	4.36	4.07	3.87	-5%
United Kingdom	0.05	0.05	0.03	0.02	0.01	-5%
Austria	1.95	2.06	2.58	0.68		-
Ireland	0.07		0.01	0.01	0.01	-
Norway	0.00	0.03	0.03	0.02		-
Armenia	0.38		1.88		0.28	
Romania	0.10	0.10	0.12			
Spain	1.56			1.53	1.30	
Azerbaijan		0.00		0.00		
Bosnia / Herzegovina			0.02	0.03		
Denmark	0.00				0.01	
Georgia	0.00			0.00		
Hungary		0.48			0.32	
Latvia			0.00	0.00		
Moldova	0.09			0.26		
Portugal	0.14				0.62	
Serbia and Montenegro			0.07		2.19	
Albania	1.29					
Andorra		0.00				
Estonia	0.02					
Former Yug. Rep. Macedonia			0.04			
Cyprus						
Liechtenstein						
Lithuania						
Malta						
Montenegro						
Russian Federation						
San Marino						
Turkey						
Ukraine						



3.8: There are 11 out of the 21 countries with four or more entries that show a significant trend. Of these eleven there are two upward and nine downward trends (Greece(+), Iceland(+), Belgium(+), France(-), Germany(-), Italy(-), Netherlands(-), Poland(-), Sweden(-), Switzerland(-), United Kingdom(-)). Most of these trends are highly significant. There is also a statistically significant general trend of $-0.07 \log_{10}$, which is equivalent to a relative reduction of 14% annually (95% CI 8.8%-18%).

3.9. PLATELETS PER 1000 INHABITANTS

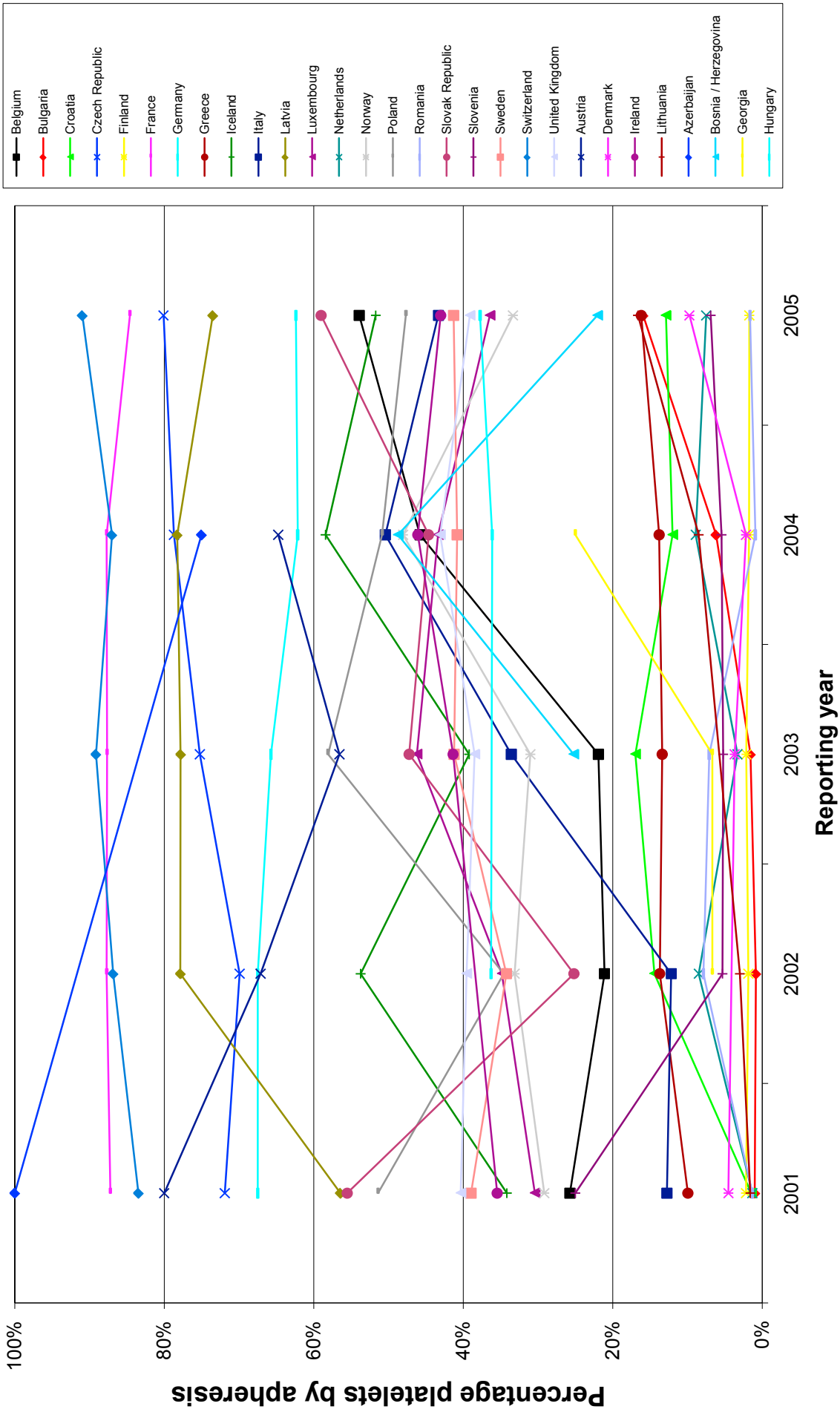
Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	4.65	4.57	4.87	5.81	6.98	10%
Bulgaria	1.38	2.02	2.16	0.71	0.70	-
Croatia	13.05	2.51	2.49	2.74	3.06	-
Czech Republic	2.11	2.29	2.19	2.37	2.10	-
Finland	6.67	6.66	6.07	6.17	6.42	-
France	3.26	3.22	3.32	3.35	3.50	10%
Germany	3.27	3.27	4.04	4.53	4.45	-
Greece	11.67	12.88	12.63	15.85	14.95	-
Iceland	3.21	2.42	3.38	3.17	3.66	-
Italy	8.26	12.84	3.37	2.16	2.75	-
Latvia	1.06	1.70	1.80	1.66	1.74	-
Luxembourg	4.15	4.06	18.42	4.83	4.79	-
Netherlands	9.39	3.45	2.92	3.23	3.19	-
Norway	3.43	3.12	2.99	3.48	3.39	-
Poland	0.94	1.49	1.04	1.30	1.62	-
Romania	1.57	1.84	1.84	2.72	3.13	5%
Slovak Republic	1.36	1.72	1.60	1.60	1.87	-
Slovenia	14.00	11.92	11.07	13.08	13.96	-
Sweden	3.52	3.79	3.63	3.90	3.67	-
Switzerland	2.43	2.02	3.12	2.51	2.69	-
United Kingdom	4.50	4.42	4.53	4.44	4.39	-
Austria	2.44	3.83	4.89	3.16		-
Denmark	4.14		18.95	6.37	5.23	-
Georgia	0.00	0.30	0.30	0.40		-
Hungary	12.31	9.24		1.43	1.46	-
Ireland	3.50		4.22	4.49	4.66	10%
Lithuania	5.81	6.56		4.19	1.35	-
Armenia	0.00		0.02		0.12	
Azerbaijan	0.00	0.01		0.02		
Bosnia / Herzegovina			0.76	0.66	1.43	
Moldova	0.30			0.09	0.94	
Spain	13.51			2.92	2.61	
Portugal	7.17				1.74	
Serbia and Montenegro			1.58		1.69	
Turkey	0.58				1.95	
Andorra		0.20				
Cyprus	13.96					
Estonia	1.98					
Former Yug. Rep. Macedonia			0.76			
Malta				38.25		
Montenegro					0.00	
Ukraine			0.12			
Albania						
Liechtenstein						
Russian Federation						
San Marino						



3.9: There are 4 out of the 27 countries with four or more entries that show a significant trend. All of these are upward trends (Belgium, France, Romania, Ireland). Despite the increasing trend in these countries, there is an overall statistically significant general downward trend (p-value of 0.02) of -0.28 platelet units per year (95% CI -0.50-0.054).

3.10. PERCENTAGE PLATELETS BY APHERESIS

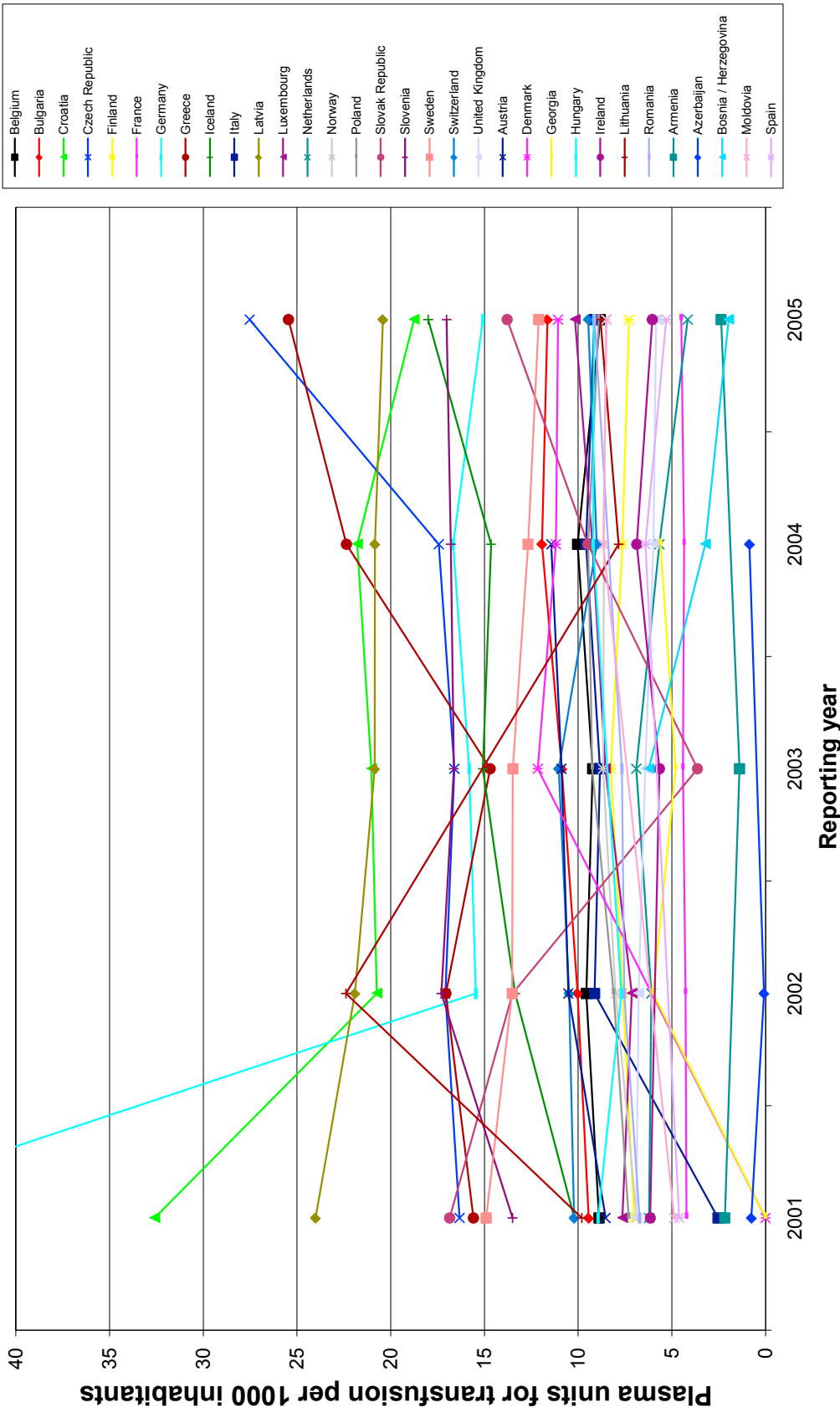
Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	26	21	22	46	54	-
Bulgaria	1	1	2	6	16	10%
Croatia	1	14	17	12	13	-
Czech Republic	72	70	75	79	80	10%
Finland	2	2	2	2	2	-10%
France	87	88	88	88	85	-
Germany	67	67	66	62	62	-
Greece	10	14	13	14	16	10%
Iceland	34	54	39	58	52	-
Italy	13	12	34	50	43	-
Latvia	56	78	78	78	73	-
Luxembourg	30	35	46	43	36	-
Netherlands	1	8	3	9	7	-
Norway	29	33	31	48	33	-
Poland	51	35	58	51	48	-
Romania	1	8	7	1	2	-
Slovak Republic	56	25	47	45	59	-
Slovenia	25	5	5	5	7	-
Sweden	39	34	41	41	41	-
Switzerland	83	87	89	87	91	10%
United Kingdom	40	40	38	43	39	-
Austria	80	67	57	65		-
Denmark	5		4	2	10	-
Ireland	35		41	46	43	-
Lithuania	2	3		8	17	10%
Azerbaijan	100			75		
Bosnia / Herzegovina			25	49	22	
Georgia		7	7	25		
Hungary		36		36	38	
Armenia			100		100	
Moldova						
Portugal	1				12	
Serbia and Montenegro					7	
Spain				35	33	
Turkey	69				28	
Andorra						
Estonia	15					
Former Yug. Rep. Macedonia			6			
Malta				2		
Montenegro						
Ukraine						
Albania						
Cyprus						
Liechtenstein						
Russian Federation						
San Marino						



3.10: There are 6 out of the 25 countries with four or more entries that show a significant trend. Of these six there are five upward and one downward trend (Bulgaria(+), Czech Republic(+), Greece(+), Switzerland(+), Lithuania(+), Lithuania(-), Finland(-)). There is a statistically significant general increase of 1.7% per year (p-value of 0.01, 95% CI 0.5%-3.0%).

3.11. FFP USE PER 1000 INHABITANTS

Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	8.9	9.6	9.2	10.0	8.8	-
Bulgaria	9.4	10.0	10.9	11.9	11.6	10%
Croatia	32.6	20.7	21.0	21.8	18.8	-
Czech Republic	16.3	17.1	16.6	17.4	27.5	10%
Finland	7.0	7.6	8.2	7.6	7.3	-
France	4.2	4.3	4.4	4.3	4.5	10%
Germany	51.5	15.5	15.8	16.7	15.1	-
Greece	15.6	17.1	14.7	22.4	25.5	-
Iceland	10.2	13.4	15.1	14.6	18.0	10%
Italy	2.5	9.1	8.8	9.6	9.1	-
Latvia	24.0	21.9	20.9	20.8	20.4	-5%
Luxembourg	7.6	7.1	8.5	9.2	10.2	10%
Netherlands	6.2	6.1	6.9	5.7	4.2	-
Norway	6.9	8.0	8.7	8.6	8.5	-
Poland	7.3	8.1	9.2	9.5	8.9	-
Slovak Republic	16.9	13.5	3.6	9.5	13.8	-
Slovenia	13.5	17.3	16.6	16.8	17.0	-
Sweden	14.9	13.5	13.5	12.7	12.1	-5%
Switzerland	10.2	10.5	11.0	9.0	9.5	-
United Kingdom	6.9	6.8	6.4	6.0	5.8	-5%
Austria	8.5	10.5	10.9	11.4		10%
Denmark	0.0		12.2	11.2	11.1	-
Georgia	0.0	6.0	4.8	5.6		-
Hungary	8.9	7.7		9.2	9.2	-
Ireland	6.2		5.7	6.9	6.0	-
Lithuania	9.8	22.4		7.8	8.8	-
Romania	6.7	7.5	7.7		9.1	10%
Armenia	2.2		1.4		2.4	
Azerbaijan	0.8	0.1		0.9		
Bosnia / Herzegovina			6.2	3.2	2.0	
Moldova	4.9			8.7	8.5	
Spain	4.6			6.4	5.3	
Portugal	0.4				0.2	
Serbia and Montenegro			14.2		15.6	
Turkey	4.5				5.6	
Andorra		0.8				
Cyprus	10.7					
Estonia	21.4					
Malta				37.6		
Montenegro					0.0	
Ukraine			0.5			
Albania						
Former Yug. Rep. Macedonia						
Liechtenstein						
Russian Federation						
San Marino						

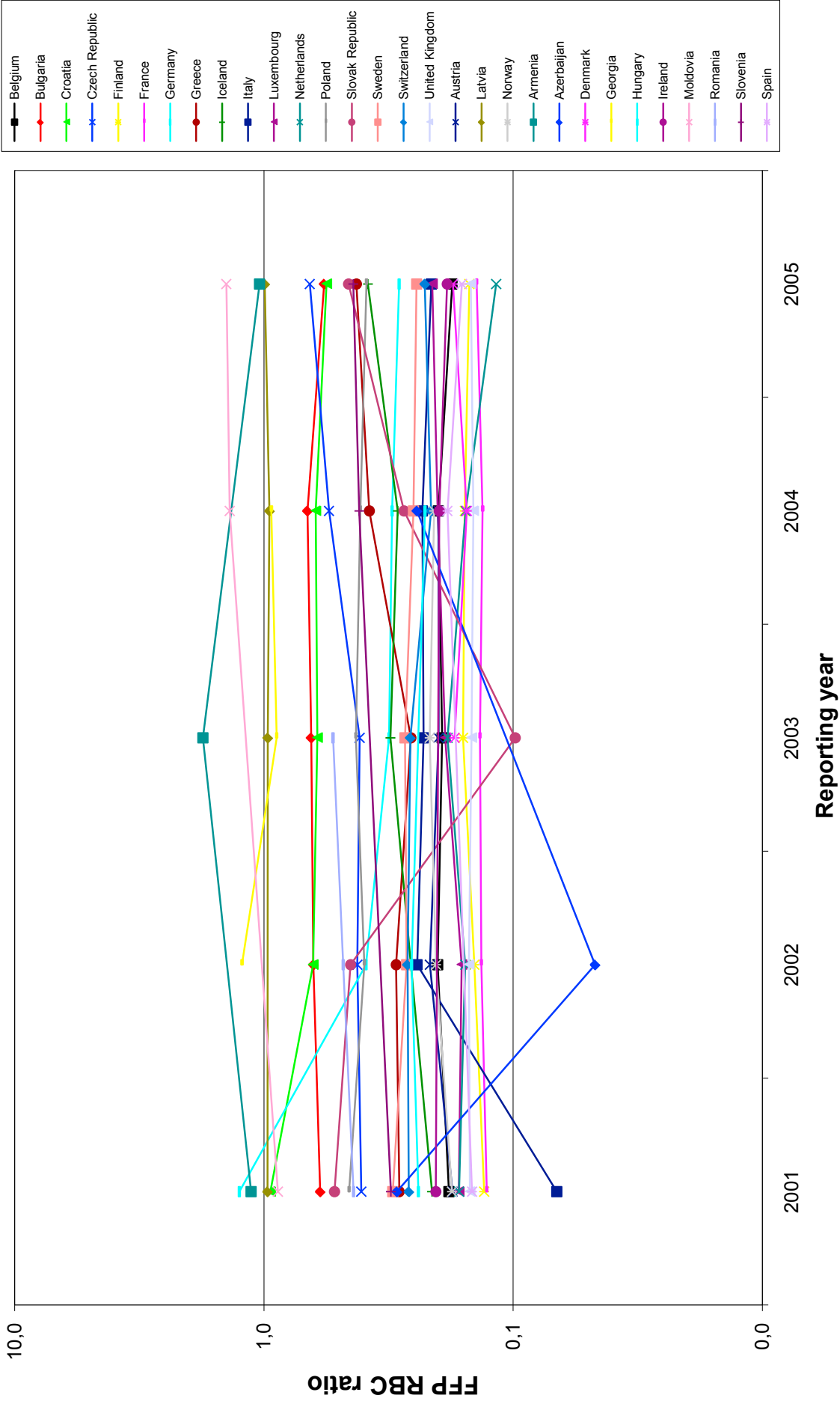


3.11: There are 10 out of the 27 countries with four or more entries that show a significant trend. Of these ten there are seven upward and three downward trends (Bulgaria(+), Czech Republic(+), France(+), Iceland(+), Luxembourg(+), Austria(+), Latvia(+), Romania(+), Sweden(-), United Kingdom(-)).

There is no statistically significant general trend. However, in two thirds of the countries there is an inclination over time. When the first observation from Germany is discarded, there is an almost significant increasing trend of 0.29 FFP units per 1000 inhabitants per year (p-value of 7%, 95% CI -0.03-0.61).

3.12. FFP RBC RATIO

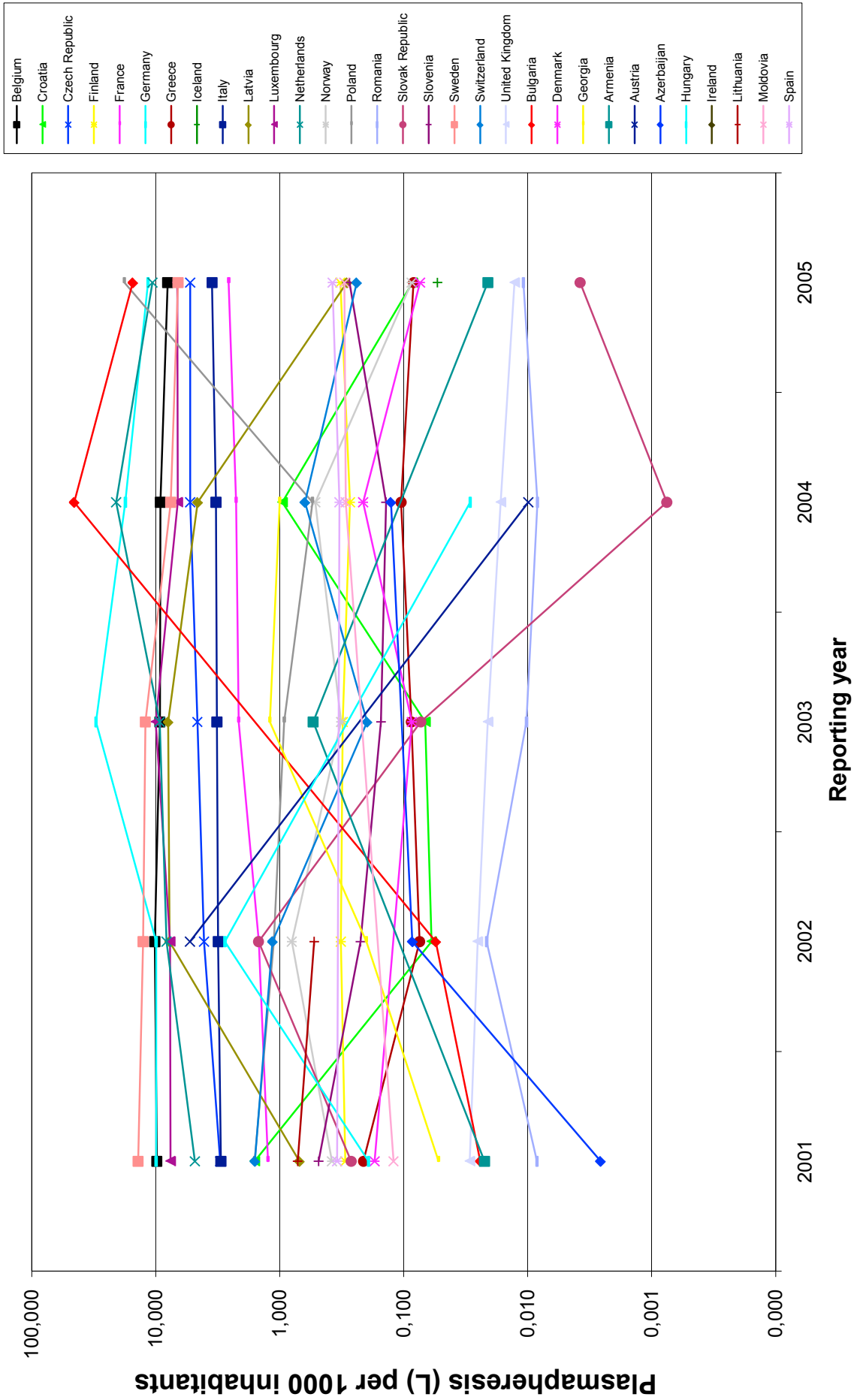
Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	0.18	0.20	0.19	0.20	0.18	-
Bulgaria	0.59	0.63	0.65	0.67	0.57	-
Croatia	0.94	0.64	0.61	0.62	0.56	-10%
Czech Republic	0.41	0.42	0.41	0.55	0.66	10%
Finland	0.13	0.14	0.16	0.16	0.15	-
France	0.13	0.13	0.14	0.13	0.14	-
Germany	1.26	0.39	0.31	0.31	0.29	-5%
Greece	0.29	0.29	0.26	0.38	0.43	-
Iceland	0.21	0.26	0.31	0.29	0.38	10%
Italy	0.07	0.24	0.23	0.23	0.21	-
Luxembourg	0.17	0.16	0.19	0.20	0.21	10%
Netherlands	0.16	0.16	0.18	0.15	0.12	-
Poland	0.46	0.39	0.43	0.41	0.39	-
Slovak Republic	0.52	0.45	0.10	0.27	0.46	-
Sweden	0.30	0.27	0.27	0.25	0.24	-10%
Switzerland	0.26	0.27	0.26	0.21	0.23	-
United Kingdom	0.15	0.15	0.15	0.14	0.15	-
Austria	0.18	0.22	0.20	0.20		-
Latvia	0.97		0.96	0.95	0.99	-
Norway	0.18	0.20	0.22	0.21		-
Armenia	1.13		1.76		1.04	
Azerbaijan	0.29	0.05		0.24		
Denmark			0.17	0.15	0.17	
Georgia		1.22	0.89	0.93		
Hungary	0.24	0.26		0.23		
Ireland	0.20			0.20	0.18	
Moldova	0.88			1.37	1.42	
Romania	0.44	0.48	0.53			
Slovenia	0.31			0.41	0.44	
Spain	0.15			0.18	0.16	
Bosnia / Herzegovina			0.68	0.34		
Lithuania	0.53	0.51				
Portugal	0.04				0.00	
Serbia and Montenegro			0.67		0.50	
Albania	0.79					
Andorra		0.07				
Cyprus	0.15					
Estonia	0.58					
Malta				1.00		
Turkey	0.36					
Ukraine			1.01			
Former Yug. Rep. Macedonia						
Liechtenstein						
Montenegro						
Russian Federation						
San Marino						



3.12: There are 6 out of the 20 countries with four or more entries that show a significant trend. Of these six there are three upward and three downward trends (Czech Republic(+), Iceland(+), Luxembourg(+), Croatia(-), Germany(-), Sweden(-)). There is no statistically significant general trend.

3.13. PLASMAPHERESIS (L) PER 1000 INHABITANTS

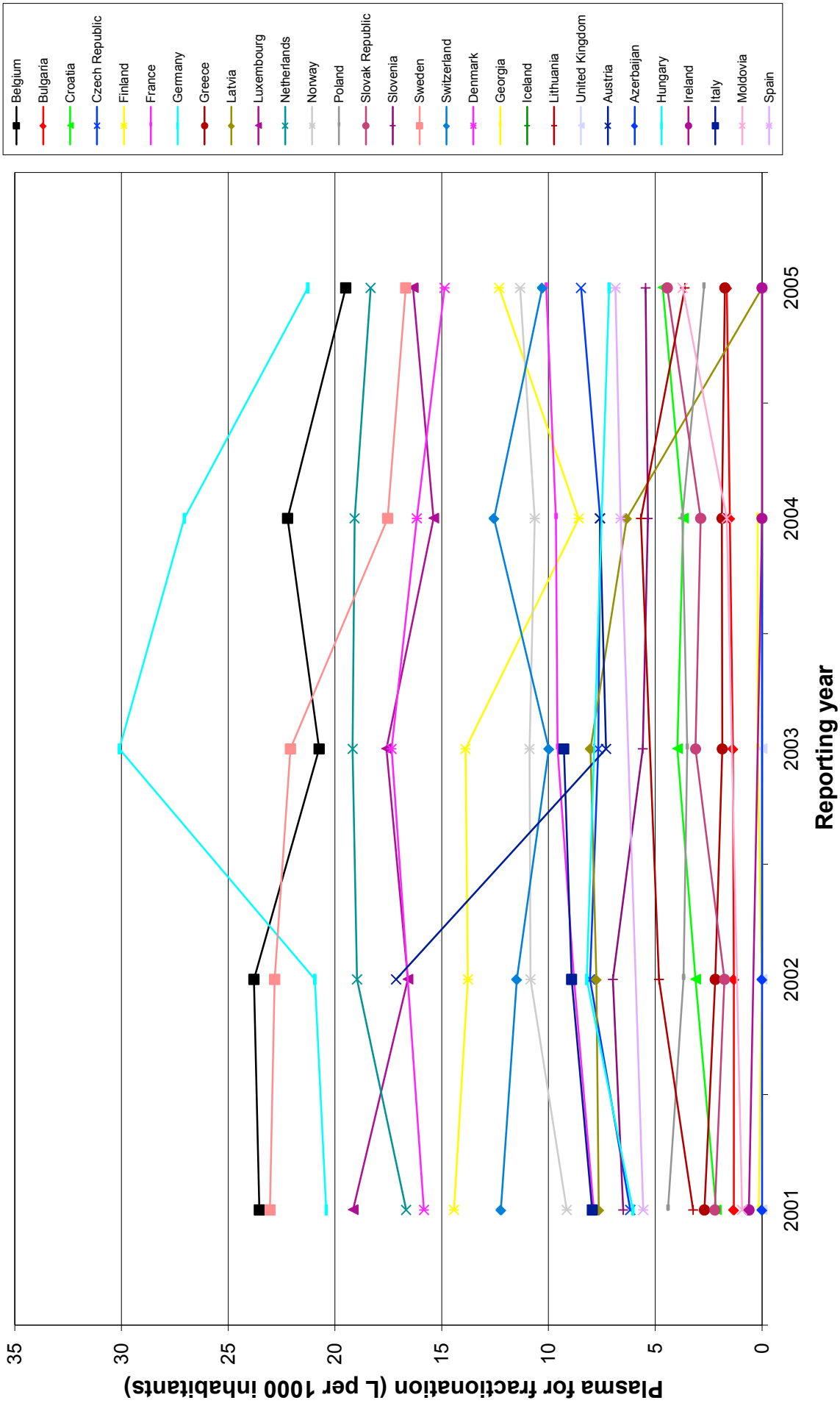
Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	9.79	10.17	9.25	9.17	7.99	-10%
Croatia	1.59	0.06	0.07	0.95	0.08	-
Czech Republic	3.02	4.08	4.61	5.26	5.26	10%
Finland	0.30	0.32	0.31	0.27	0.32	-
France	1.24	1.47	2.14	2.24	2.58	5%
Germany	9.92	9.92	30.29	17.55	11.54	-
Greece	0.21	0.07	0.09	0.10	0.08	-
Iceland	0.00	0.00	0.00	0.00	0.05	-
Italy	2.98	3.13	3.21	3.26	3.51	5%
Latvia	0.69	7.71	7.93	4.58	0.29	-
Luxembourg	7.59	7.65	9.99	6.64	6.69	-
Netherlands	4.83	8.17	9.27	20.81	10.61	10%
Norway	0.38	0.80	0.32	0.52	0.09	-
Poland	1.59	1.12	0.92	0.54	17.90	-
Romania	0.01	0.02	0.01	0.01	0.01	-
Slovak Republic	0.27	1.48	0.07	0.00	0.00	-
Slovenia	0.49	0.22	0.15	0.14	0.27	-
Sweden	13.86	12.64	12.11	7.56	6.60	-5%
Switzerland	1.59	1.14	0.20	0.63	0.24	-
United Kingdom	0.03	0.03	0.02	0.02	0.01	-5%
Bulgaria	0.02	0.06	.	45.43	15.27	-
Denmark	0.17	.	0.09	0.21	0.07	-
Georgia	0.05	0.20	1.20	1.00	.	-
Armenia	0.02	.	0.54	.	0.02	
Austria	.	5.29	0.00	0.01	.	
Azerbaijan	0.00	0.09	.	0.13	.	
Hungary	0.19	2.76	.	0.03	.	
Ireland	0.00	.	0.00	.	0.00	
Lithuania	0.72	0.53	.	0.00	.	
Moldova	0.12	.	.	0.29	0.30	
Spain	0.34	.	.	0.33	0.37	
Andorra	.	0.00	.	.	.	
Bosnia / Herzegovina	.	.	.	0.00	.	
Estonia	0.02	
Former Yug. Rep. Macedonia	.	.	0.00	.	.	
Portugal	0.00	
Russian Federation	.	.	.	2.11	.	
Serbia and Montenegro	0.44	
Albania	
Cyprus	
Liechtenstein	
Malta	
Montenegro	
San Marino	
Turkey	
Ukraine	



3.13: There are 7 out of the 23 countries with four or more entries that show a significant trend. Of these seven there are four upward and three downward trends (Czech Republic(+), France(+), Italy(+), Netherlands(+), Belgium(-), Sweden(-), United Kingdom(-)). There is no statistically significant general trend in plasmapheresis use over time.

3.14. PLASMA FOR FRACTIONATION PER 1000 INHABITANTS

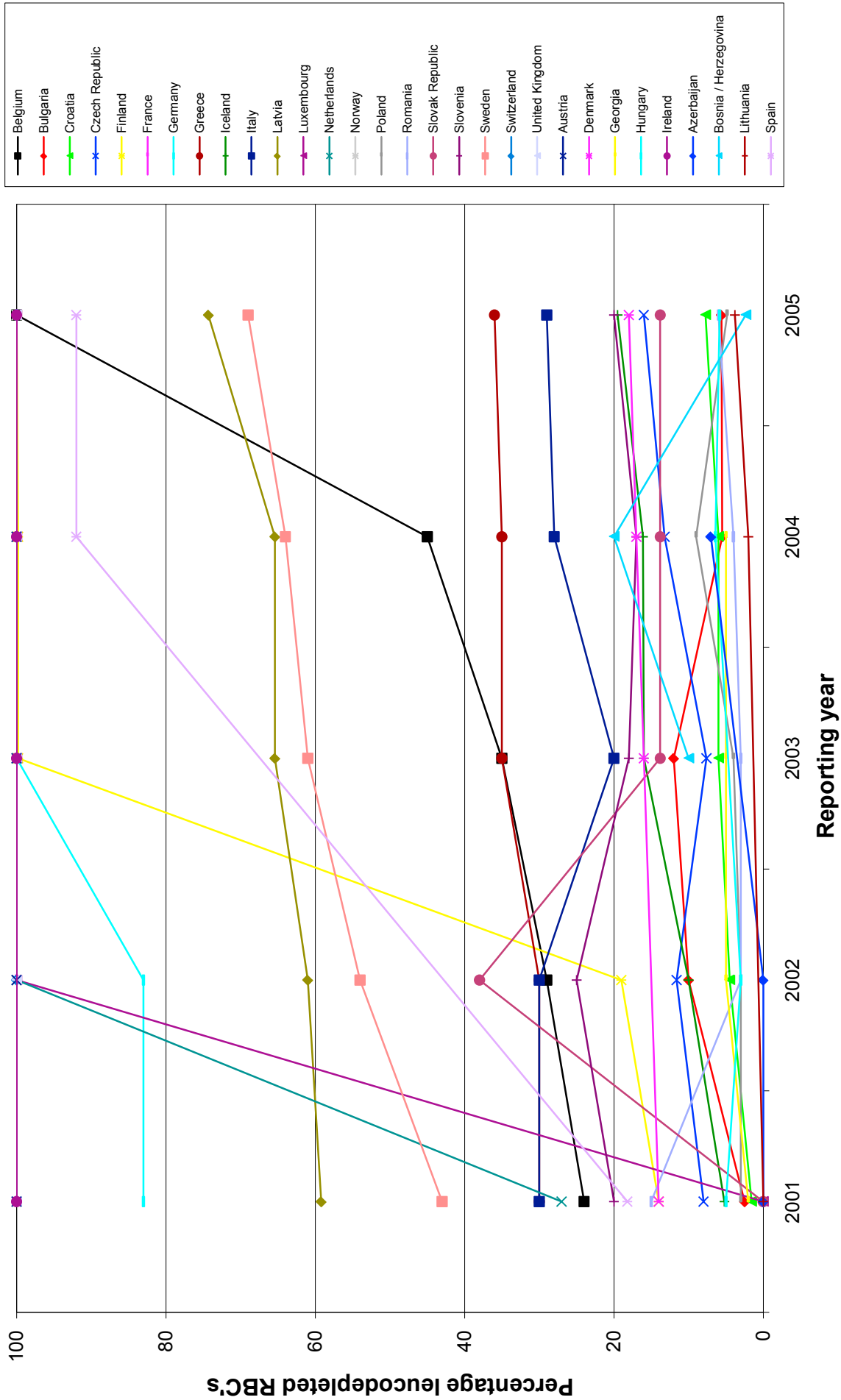
Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	23.54	23.80	20.74	22.22	19.49	-
Bulgaria	1.32	1.31	1.36	1.50	1.65	10%
Croatia	2.14	3.11	3.96	3.69	4.64	10%
Czech Republic	6.17	8.05	7.67	7.58	8.48	-
Finland	14.42	13.77	13.89	8.58	12.31	-
France	7.87	8.80	9.57	9.65	10.10	5%
Germany	20.41	20.94	30.10	27.06	21.27	-
Greece	2.69	2.19	1.86	1.88	1.74	-10%
Latvia	7.64	7.76	8.03	6.34	0.00	-
Luxembourg	19.15	16.59	17.59	15.38	16.34	-
Netherlands	16.67	18.96	19.17	19.08	18.33	-
Norway	9.15	10.84	10.89	10.65	11.33	-
Poland	4.40	3.67	3.50	3.73	2.72	-
Slovak Republic	2.21	1.75	3.11	2.87	4.44	-
Slovenia	6.50	6.98	5.58	5.35	5.45	-
Sweden	23.04	22.83	22.08	17.53	16.69	-5%
Switzerland	12.23	11.48	9.98	12.55	10.29	-
Denmark	15.83		17.35	16.16	14.87	-
Georgia	0.15	0.02	0.20	0.20		-
Iceland		0.00	0.00	0.00	0.00	-
Lithuania	3.23	4.82		5.67	3.62	-
United Kingdom	0.00	0.00	0.00		0.00	-
Austria		17.13	7.31	7.59		
Azerbaijan	0.00	0.00		0.00		
Hungary	6.05	8.21			7.16	
Ireland	0.61			0.00	0.00	
Italy	7.95	8.92	9.28			
Moldova	0.93			1.65	3.71	
Spain	5.56			6.62	6.86	
Armenia	0.00		2.82			
Bosnia / Herzegovina				0.00	1.86	
Cyprus	0.00					
Estonia	5.29					
Former Yug. Rep. Macedonia			2.17			
Portugal	0.00					
Romania	0.09					
Russian Federation				1.31		
Serbia and Montenegro					1.62	
Turkey					0.00	
Ukraine			1.79			
Albania						
Andorra						
Liechtenstein						
Malta						
Montenegro						
San Marino						



3.14: There are 5 out of the 22 countries with four or more entries that show a significant trend. Of these five there are three upward and two downward trends (Bulgaria(+), Croatia(+), France(+), Greece(-), Sweden(-)). There is no statistically significant general trend in plasma used for fractionation.

3.15. PERCENTAGE LEUCOCYTE DEPLETED RBC

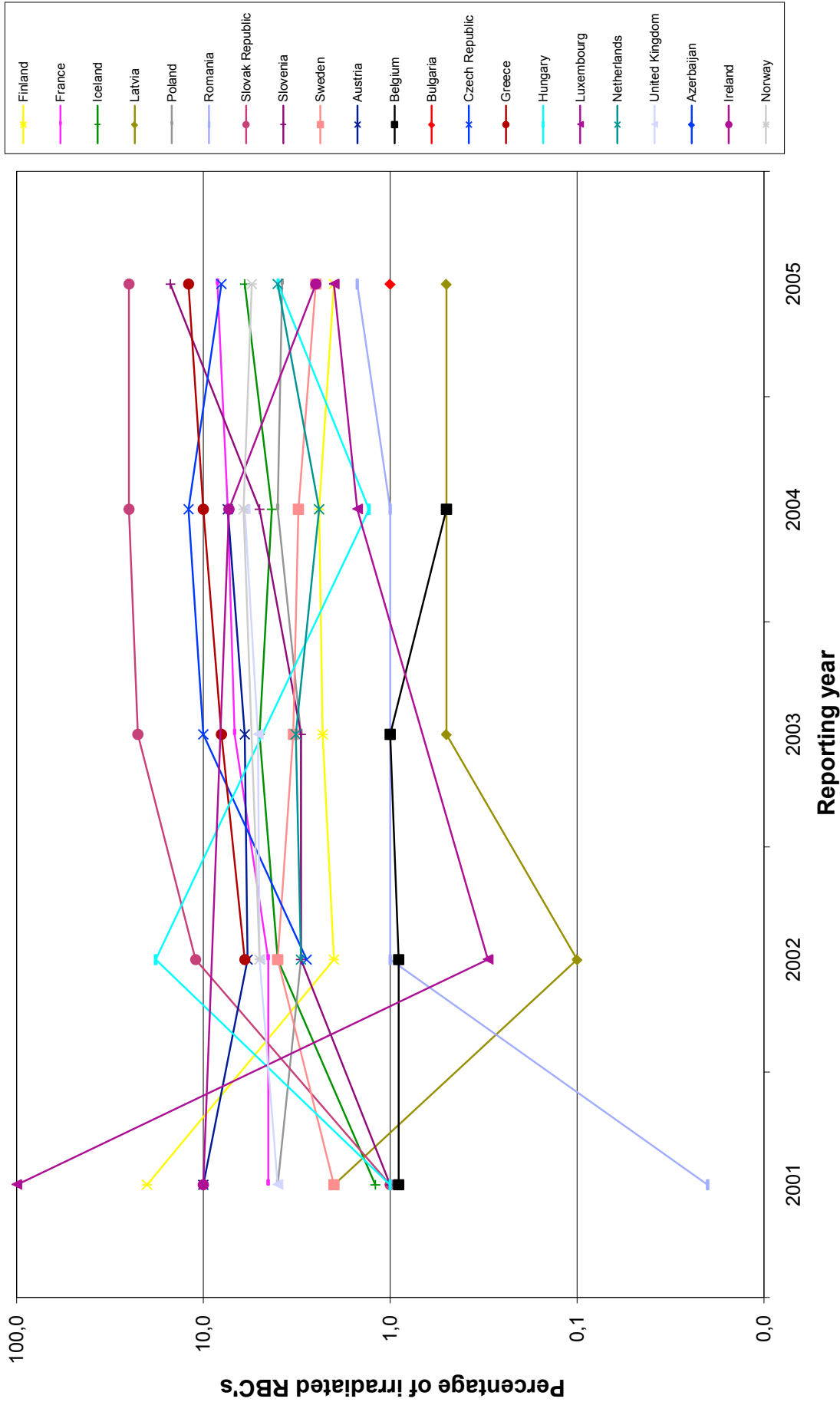
Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	24	29	35	45	100	5%
Bulgaria	3	10	12	6	6	-
Croatia	2	5	6	6	8	10%
Czech Republic	8	12	8	13	16	-
Finland	14	19	100	100	100	10%
France	100	100	100	100	100	-
Germany	83	83	100	100	100	-
Greece	30	30	35	35	36	10%
Iceland	5	10	16	16	20	5%
Italy	30	30	20	28	29	-
Latvia	59	61	65	65	74	10%
Luxembourg	0	100	100	100	100	-
Netherlands	27	100	100	100	100	-
Norway	100	100	100	100	100	-
Poland	3	3	4	9	5	-
Romania	15	3	3	4	6	-
Slovak Republic	0	38	14	14	14	-
Slovenia	20	25	18	17	20	-
Sweden	43	54	61	64	69	5%
Switzerland	100	100	100	100	100	-
United Kingdom	100	100	100	100	100	-
Austria	100	100	100	100		-
Denmark	14		16	17	18	10%
Georgia	2	5	5	5		-
Hungary	5	3		6	6	-
Ireland	100		100	100	100	-
Azerbaijan	0	0		7		
Bosnia / Herzegovina			10	20	2	
Lithuania	0			2	4	
Spain	18			92	92	
Armenia	0		0			
Portugal	100				100	
Albania	17					
Cyprus	0					
Estonia	3					
Former Yug. Rep. Macedonia			3			
Malta				100		
Moldova					0	
Serbia and Montenegro					1	
Turkey	0					
Ukraine			5			
Andorra						
Liechtenstein						
Montenegro						
Russian Federation						
San Marino						



3.15: There are 8 out of the 26 countries with four or more entries that show a significant trend, all of which are upward trends (Belgium, Croatia, Finland, Greece, Iceland, Latvia, Sweden, Denmark). There is a statistically significant general increase in the percentage of leucocyte depleted RBC's of 4.3% per year (p-value of 0.001%, 95% CI 2.5%-6.2%).

3.16. PERCENTAGE IRRADIATED RBC

Country	Year					Trend
	2001	2002	2003	2004	2005	
Finland	20.0	2.0	2.3	2.4	2.0	-
France	4.5	4.5	6.8	7.4	8.4	10%
Iceland	1.2	4.0	5.0	4.3	6.0	10%
Latvia	2.0	0.1	0.5	0.5	0.5	-
Poland	4.0	3.0	3.0	4.0	3.8	-
Romania	0.0	1.0	1.0	1.0	1.5	-
Slovak Republic	1.0	11.0	22.4	25.0	25.0	10%
Slovenia	1.0	3.0	3.0	5.0	15.0	10%
Sweden	2.0	4.0	3.3	3.1	2.5	-
Austria	10.0	5.8	6.0	7.4		-
Belgium	0.9	0.9	1.0	0.5		-
Bulgaria	0.0	0.0	0.0		1.0	-
Czech Republic		2.8	10.0	12.0	8.0	-
Greece		6.0	8.0	10.0	12.0	10%
Hungary	1.0	18.0		1.3	4.0	-
Luxembourg	100.0	0.3		1.5	2.0	-
Netherlands		3.0	3.2	2.4	4.0	-
United Kingdom	4.0	5.0	5.1	6.0		10%
Azerbaijan	0.0	0.0		0.0		
Ireland	10.0			7.3	2.5	
Norway		5.0		6.1	5.5	
Armenia	0.0		0.0			
Bosnia / Herzegovina			50.0	2.0		
Georgia	0.0			0.0		
Germany				3.2	3.0	
Italy				7.0	8.0	
Lithuania	0.6			1.3		
Albania	0.0					
Croatia		0.0				
Cyprus	0.0					
Estonia	0.3					
Former Yug. Rep. Macedonia			0.0			
Malta				1.0		
Moldova					0.0	
Portugal					15.0	
Serbia and Montenegro					0.2	
Turkey	0.0					
Andorra						
Denmark						
Liechtenstein						
Montenegro						
Russian Federation						
San Marino						
Spain						
Switzerland						
Ukraine						

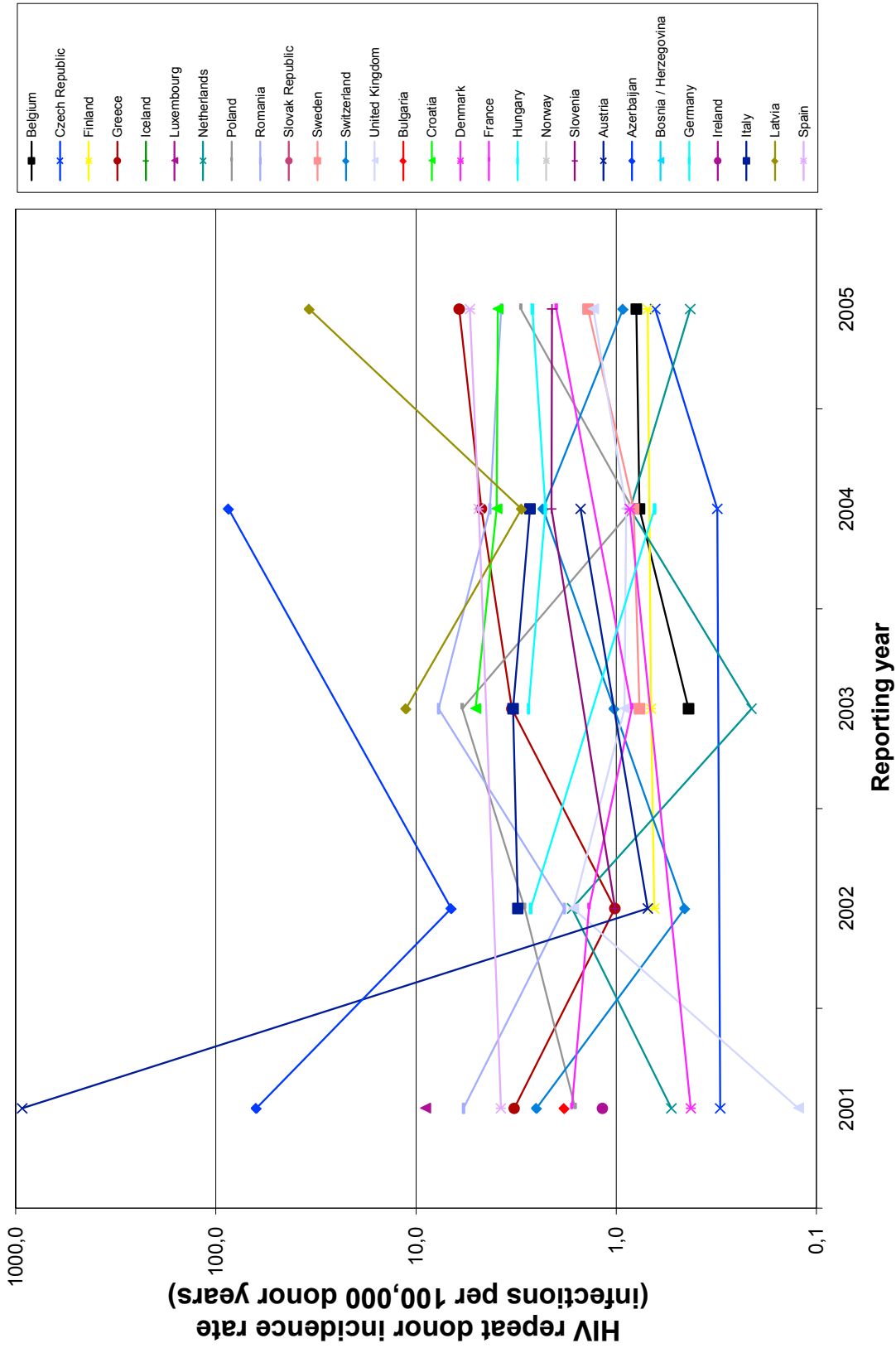


3.16: There are 6 out of the 18 countries with four or more entries that show a significant trend, all of which are upward trends (France, Iceland, Slovak Republic, Slovenia, Greece, United Kingdom). There is a statistically significant general increase of 0.83% per year (p-value of 0.001, 95% CI 0.3%-1.3%). There is clearly a dominant impact of Slovak Republic: excluding this country from the analysis results in a general trend of 0.46% per year (p-value of 0.007, 95% CI 0.13%-0.79%). The relative increase over time is 25% (0.1 log10), p-value 0.0004, 95% CI 11%-41%).

3.17. HIV REPEAT DONOR INCIDENCE RATE

Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	0.00	0.00	0.43	0.76	0.79	10%
Czech Republic	0.30	0.00	0.00	0.31	0.64	-
Finland	0.00	0.65	0.67	0.00	0.70	-
Greece	3.23	1.02	3.32	4.72	6.08	10%
Iceland	0.00	0.00	0.00	0.00	0.00	-
Luxembourg	8.98	0.00	0.00	0.00	0.00	-
Netherlands	0.53	1.66	0.21	0.85	0.43	-
Poland	1.60	2.87	5.88	0.83	3.00	-
Romania	5.79	1.82	7.71	4.28	3.75	-
Slovak Republic	0.00	0.00	0.00	0.00	0.00	-
Sweden	0.00	0.00	0.76	0.82	1.38	10%
Switzerland	2.50	0.45	1.03	2.32	0.92	-
United Kingdom	0.12	1.64	0.91	0.89	1.30	-
Bulgaria	1.82	0.00	0.00	0.00		-
Croatia		0.00	5.04	3.96	3.90	-
Denmark	0.42		0.00	0.85	0.00	-
France	1.67	1.37	0.84		1.99	-
Hungary	0.00	2.68		0.64	0.00	-
Norway		0.00	0.00	0.00	0.00	-
Slovenia		1.01	0.00	2.11	2.09	-
Austria	928.0	0.70		1.51		
Azerbaijan	62.81	6.67		86.38		
Bosnia / Herzegovina			0.00	0.00	0.00	
Germany			2.74	2.26	2.62	
Ireland	1.17			0.00	0.00	
Italy		3.10	3.27	2.70		
Latvia			11.23	2.97	34.19	
Spain	3.77			4.86	5.38	
Georgia		0.00		42.86		
Lithuania		55.75		0.00		
Moldova	0.00				0.00	
Armenia			195.82			
Estonia	4.93					
Portugal	3.84					
Albania						
Andorra						
Cyprus						
Former Yug. Rep. Macedonia						
Liechtenstein						
Malta						
Montenegro						
Russian Federation						
San Marino						
Serbia and Montenegro						
Turkey						
Ukraine						

*Incidence rate as the number of infections per 100,000 donor years

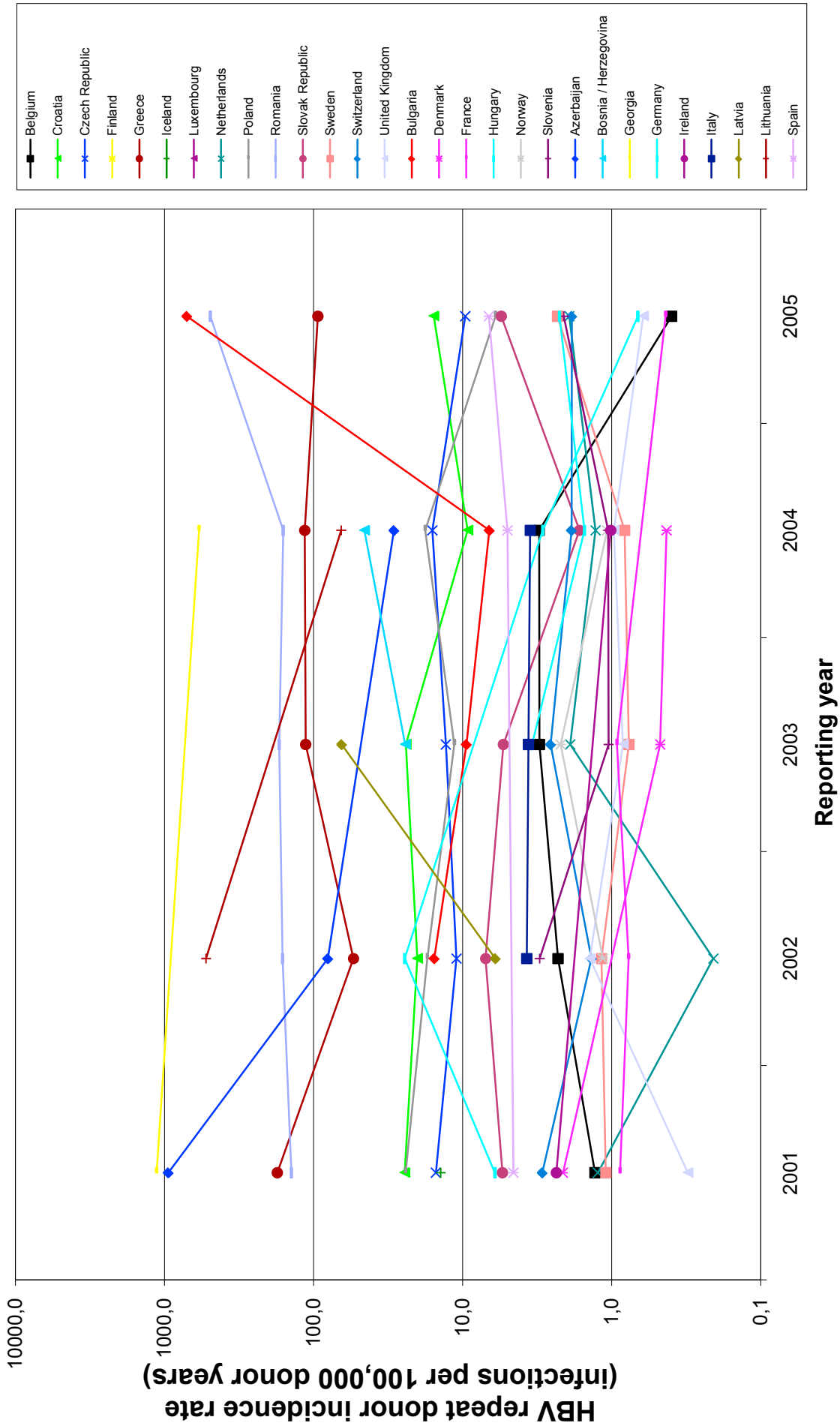


3.17: The incidence rate is calculated by dividing the number of reported donor infections by the total number of donors in the reporting year. There are 3 out of the 20 countries with four or more entries that show a significant trend., all of which are upward trends (Belgium, Greece, Sweden). There is no statistically significant general trend in HIV infections amongst repeat donors.

3.18. HBV REPEAT DONOR INCIDENCE RATE

Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	1.29	2.29	3.04	3.06	0.40	-
Croatia	24.43	20.07	23.95	9.23	15.61	-
Czech Republic	15.11	10.97	12.94	15.94	9.58	-
Finland	0.00	0.00	0.00	0.00	0.00	-
Greece	174.96	53.86	112.62	114.45	93.49	-
Iceland	13.99	0.00	0.00	0.00	0.00	-
Luxembourg	0.00	0.00	0.00	0.00	0.00	-
Netherlands	1.24	0.21	1.90	1.28	1.92	-
Poland	24.05	17.21	11.34	17.79	6.00	-
Romania	140.6	161.1	169.6	159.7	492.5	-
Slovak Republic	5.39	7.00	5.32	1.64	5.49	-
Sweden	1.09	1.17	0.76	0.82	2.31	-
Switzerland	2.92	1.36	2.56	1.86	1.85	-
United Kingdom	0.31	1.40	0.84	0.97	0.61	-
Bulgaria		15.49	9.42	6.61	705.2	-
Denmark	2.12		0.47	0.43	0.00	-10%
France	0.88	0.77	0.92		0.43	-
Hungary	6.06	24.42		2.89	0.67	-
Norway		1.14	2.20	1.07	0.00	-
Slovenia		3.04	1.05	1.05	2.09	-
Azerbaijan	942.6	80.00		28.79		
Bosnia / Herzegovina			24.25	45.57	0.00	
Georgia	1127	0.00		585.7		
Germany			3.41	1.52	2.24	
Ireland	2.34			1.01	0.00	
Italy		3.70	3.61	3.51		
Latvia	0.00	6.03	64.58			
Lithuania	0.00	525.0		65.10		
Spain	4.55			4.99	6.66	
Armenia	878.3		6984			
Austria		7.30		4.14		
Albania	6913					
Estonia	4.93					
Moldova	0.00					
Montenegro					11.27	
Portugal	6.41					
Andorra						
Cyprus						
Former Yug. Rep. Macedonia						
Liechtenstein						
Malta						
Russian Federation						
San Marino						
Serbia and Montenegro						
Turkey						
Ukraine						

*Incidence rate as the number of infections per 100,000 donor years

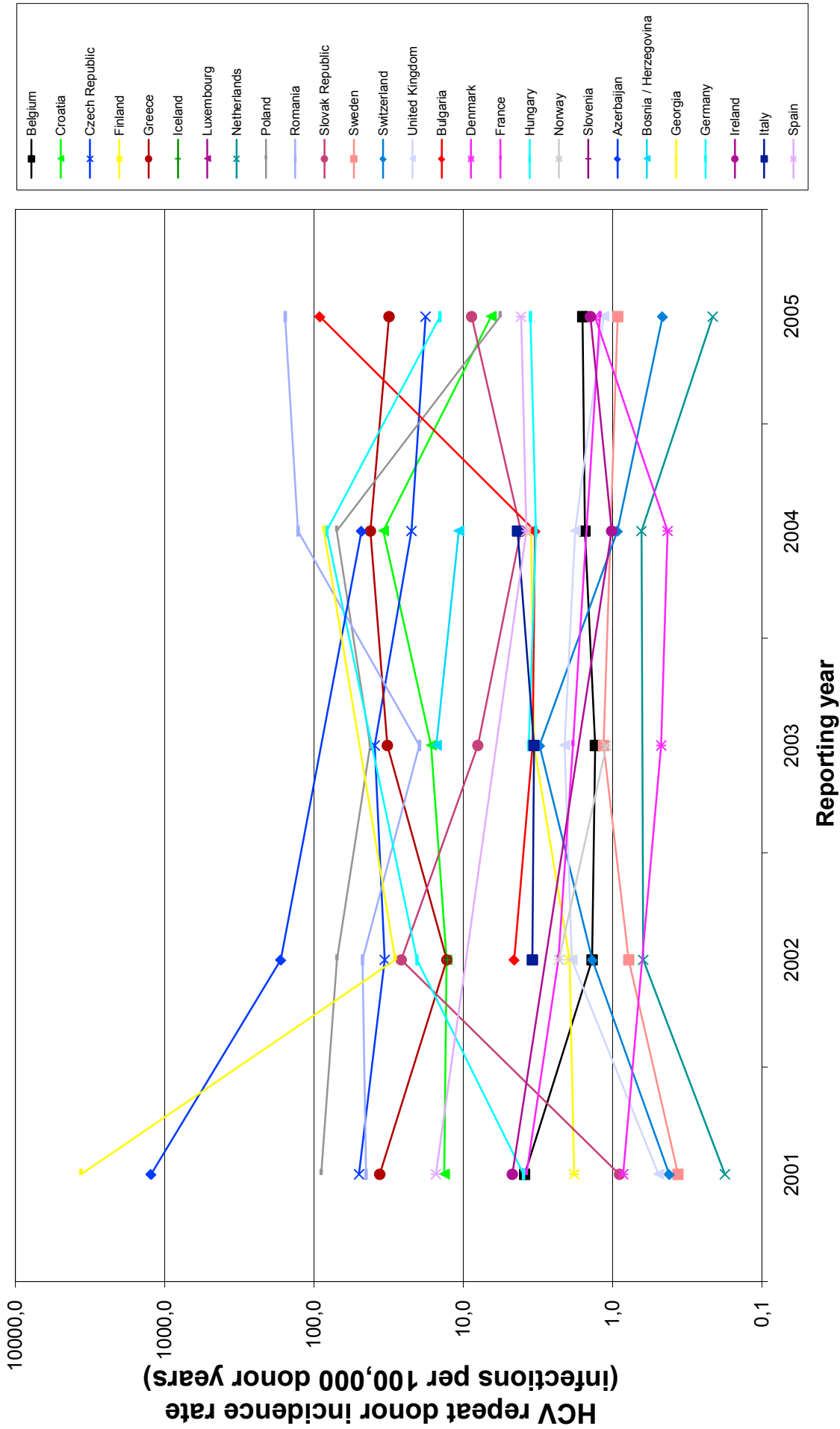


3.18: Only one out of the 20 countries with four or more entries shows a significant downward trend (Denmark). There is a statistically significant general trend of 0.05 log10, which is equivalent to an annual relative decrease of 11% (95% CI 2%-20%).

3.19. HCV REPEAT DONOR INCIDENCE RATE

Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	3.88	1.37	1.30	1.53	1.59	-
Croatia	13.38	12.90	16.39	34.28	6.51	-
Czech Republic	49.85	33.52	39.11	22.19	17.87	-10%
Finland	1.81	1.94	3.35	3.50	0.00	-
Greece	36.28	12.87	32.23	41.82	31.38	-
Iceland	0.00	12.71	0.00	0.00	0.00	-
Luxembourg	0.00	0.00	0.00	0.00	0.00	-
Netherlands	0.18	0.62	0.00	0.64	0.21	-
Poland	89.39	70.06	41.99	70.34	5.66	-
Romania	44.67	47.25	19.63	127.6	155.6	-
Slovak Republic	0.90	25.99	7.98	4.10	8.79	-
Sweden	0.36	0.78	1.15	0.00	0.92	-
Switzerland	0.42	1.36	3.08	0.93	0.46	-
United Kingdom	0.49	1.87	2.10	1.78	1.15	-
Bulgaria		4.56	3.43	3.31	90.94	-
Denmark	0.85		0.47	0.43	1.31	-
France	3.77	2.31	1.84		1.21	-10%
Hungary	3.94	20.40		81.98	14.33	-
Norway		2.29	1.10	0.00	0.00	-
Slovenia		0.00	0.00	0.00	0.00	-
Azerbaijan	1231	166.7		47.99		
Bosnia / Herzegovina			15.16	10.72	0.00	
Georgia	3629	28.57		85.71		
Germany			3.64	3.26	3.55	
Ireland	4.69			1.01	1.41	
Italy		3.45	3.36	4.33		
Spain	15.23			3.78	4.10	
Armenia	1192		4439			
Austria		11.82		6.02		
Latvia		21.11	435.2			
Lithuania		720.13		292.9		
Albania	1367					
Estonia	14.78					
Moldova	0.00					
Montenegro					22.53	
Portugal	0.00					
Andorra						
Cyprus						
Former Yug. Rep. Macedonia						
Liechtenstein						
Malta						
Russian Federation						
San Marino						
Serbia and Montenegro						
Turkey						
Ukraine						

*Incidence rate as the number of infections per 100,000 donor years

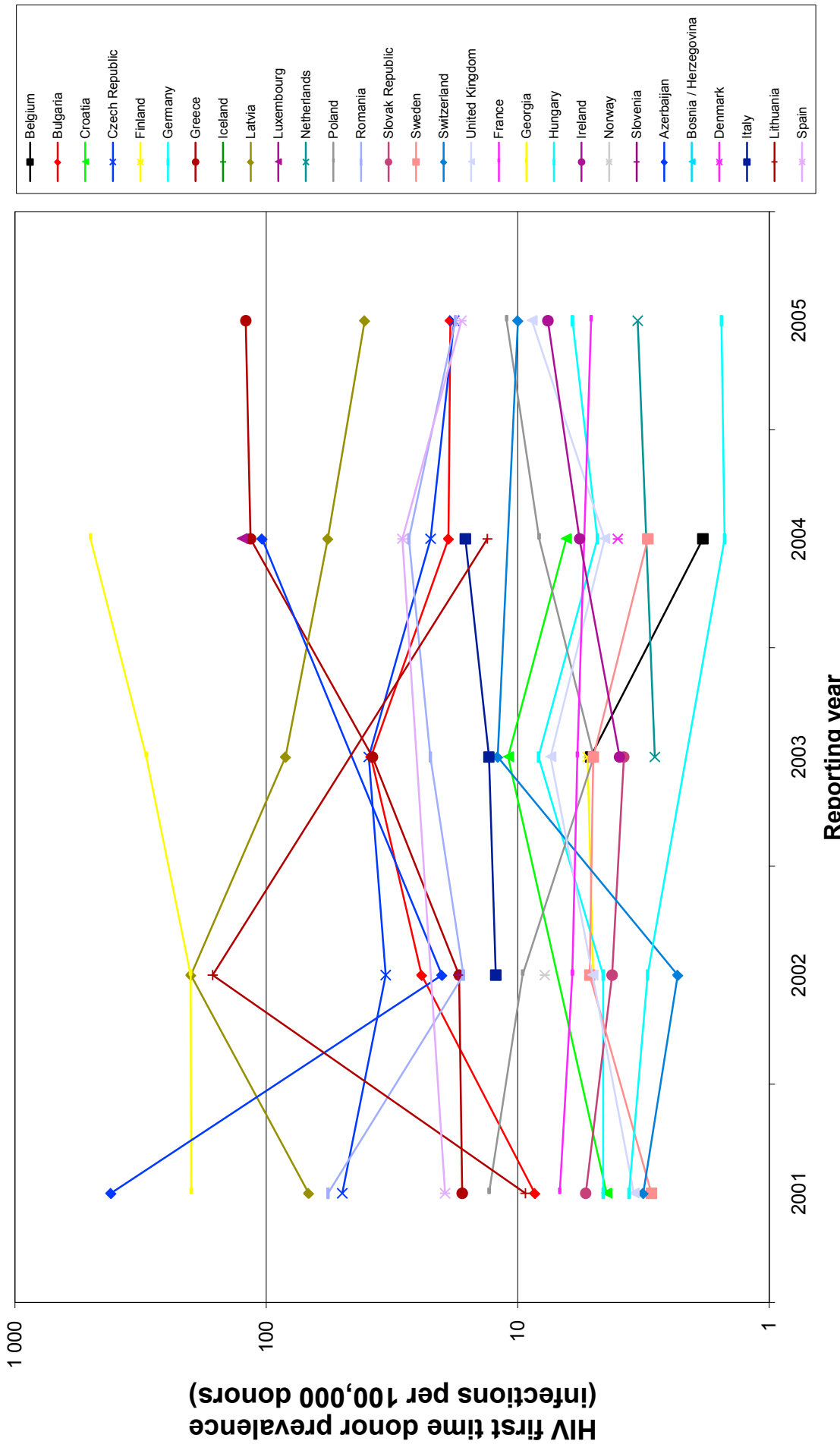


3.19: There are 2 out of the 20 countries with four or more entries which show a statistically significant decreasing trend (Czech Republic and France). There is no statistically significant general trend in HCV infections amongst repeat donors.

3.20. HIV FIRST TIME DONOR PREVALENCE

Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	0.00	0.00	5.13	1.83	0.00	-
Bulgaria	8.54	24.08	38.35	18.84	18.53	-
Croatia	4.43	0.00	10.91	6.42	0.00	-
Czech Republic	49.85	33.52	39.11	22.19	17.87	-10%
Finland	0.00	5.00	5.28	0.00	0.00	-
Germany	4.57	4.57	8.26	4.82	6.06	-
Greece	16.63	17.09	37.81	115.4	120.6	5%
Iceland	0.00	0.00	0.00	0.00	0.00	-
Latvia	67.82	199.5	83.77	56.87	40.56	-
Luxembourg	0.00	0.00	0.00	124.8	0.00	-
Netherlands	0.00	0.00	2.85	0.00	3.33	-
Poland	12.99	9.55	4.98	8.22	11.06	-
Romania	56.82	16.45	22.25	27.10	17.69	-
Slovak Republic	5.36	4.21	3.78	0.00	0.00	-10%
Sweden	2.94	5.17	5.00	3.04	0.00	-
Switzerland	3.17	2.31	12.01	0.00	9.97	-
United Kingdom	3.45	5.03	7.40	4.51	8.78	-
France	6.81	6.06	5.79		5.11	-10%
Georgia	199	200	300	500		10%
Hungary	3.61	3.04		1.50	1.55	-
Ireland	0.00		3.94	5.67	7.59	10%
Norway		7.80	0.00	0.00	0.00	-
Slovenia		17.25	0.00	0.00	0.00	-
Azerbaijan	415.0	20.00		103.9		
Bosnia / Herzegovina			0.00	0.00	0.00	
Denmark	0.00		0.00	4.00		
Italy		12.23	13.01	16.14		
Lithuania	9.31	163.35		13.20		
Spain	19.43			28.74	16.72	
Armenia	26.11		459.3			
Austria		0.00		2.13		
Moldova	64.26				59.79	
Albania	53.62					
Andorra		0.00				
Estonia	111.9					
Former Yug. Rep. Macedonia			633.0			
Malta				0.00		
Montenegro					21.52	
Portugal	34.26					
Cyprus						
Liechtenstein						
Russian Federation						
San Marino						
Serbia and Montenegro						
Turkey						
Ukraine						

*Prevalence as the number of infections per 100,000 donors

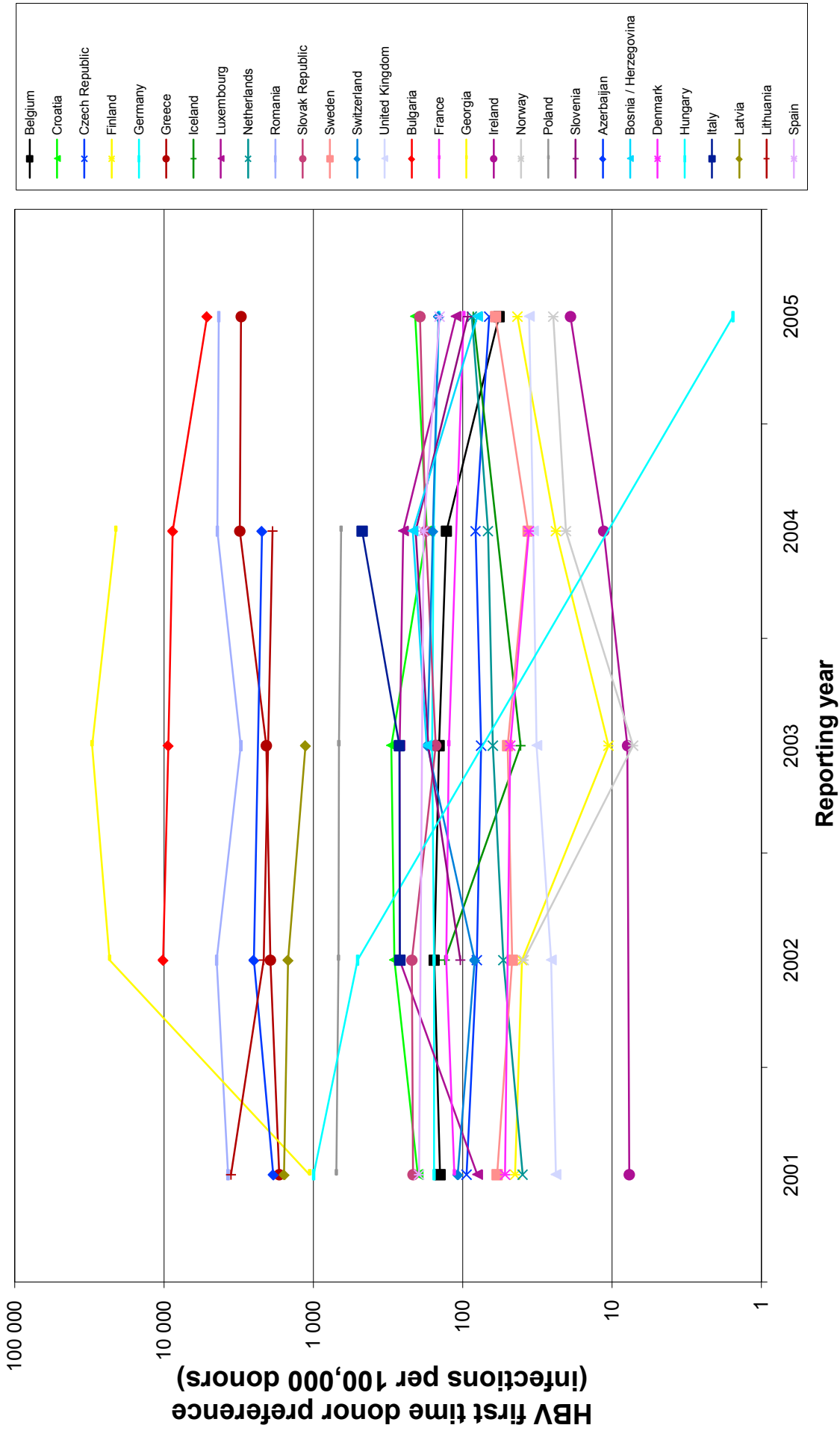


3.20: There are 6 out of the 23 countries with four or more entries that show a significant trend. Of these six there are three upward and three downward trends (Greece(+), Georgia(+), Ireland(+), Czech Republic(-), Slovak Republic(-), France(-)). There is no statistically significant general trend in first time donor HIV prevalence.

3.21. HBV FIRST TIME DONOR PREVALENCE

Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	141.8	155.0	143.6	128.4	57.03	-
Croatia	199.3	286.7	300.0	173.3	207.5	-
Czech Republic	94.18	80.33	75.08	81.91	66.25	-
Finland	44.55	40.02	10.56	23.73	42.89	-
Germany	155.5	155.5	160.1	156.6	144.1	-
Greece	1,691	1,939	2,064	3,104	3,044	10%
Iceland	0.00	131.49	40.97	0.00	84.75	-
Luxembourg	79.62	263.9	263.9	249.7	111.0	-
Netherlands	40	53	63	68	87	5%
Romania	3,724	4,442	3,055	4,389	4,291	-
Slovak Republic	214.6	218.9	151.3	176.5	192.8	-
Sweden	58.73	46.51	50.01	36.44	60.17	-
Switzerland	107.7	83.08	172.1	158.1	144.6	-
United Kingdom	23.75	26	32	34	36	5%
Bulgaria		10,129	9,356	8,737	5,146	-10%
France	113.6	128.5	123.7		98.20	-
Georgia	1,057	23,100	30,300	21,000		-
Ireland	7.65		7.87	11.34	18.97	10%
Norway		39.02	7.22	20.35	24.71	-
Poland	700.9	677.8	674.2	651.5		-10%
Slovenia		103.5	169.8	206.0	92.49	-
Azerbaijan	1,851	2,500		2,204		
Bosnia / Herzegovina			174.3	215.6	79.67	
Denmark	52.00		48.00	36.00		
Hungary	994.2	505.0			1.55	
Italy		263.2	265.4	470.4		
Latvia	1,568	1,477	1,127.10			
Lithuania	3,557	2,148		1,874		
Spain	195.8			183.0	142.6	
Armenia	1,749		565.3			
Austria		126.1		81.10		
Albania	7,212					
Andorra		0.00				
Estonia	581.85					
Former Yug. Rep. Macedonia			2,544			
Malta				139.3		
Moldova	23,039					
Montenegro					860.8	
Portugal	261.6					
Cyprus						
Liechtenstein						
Russian Federation						
San Marino						
Serbia and Montenegro						
Turkey						
Ukraine						

*Prevalence as the number of infections per 100,000 donors

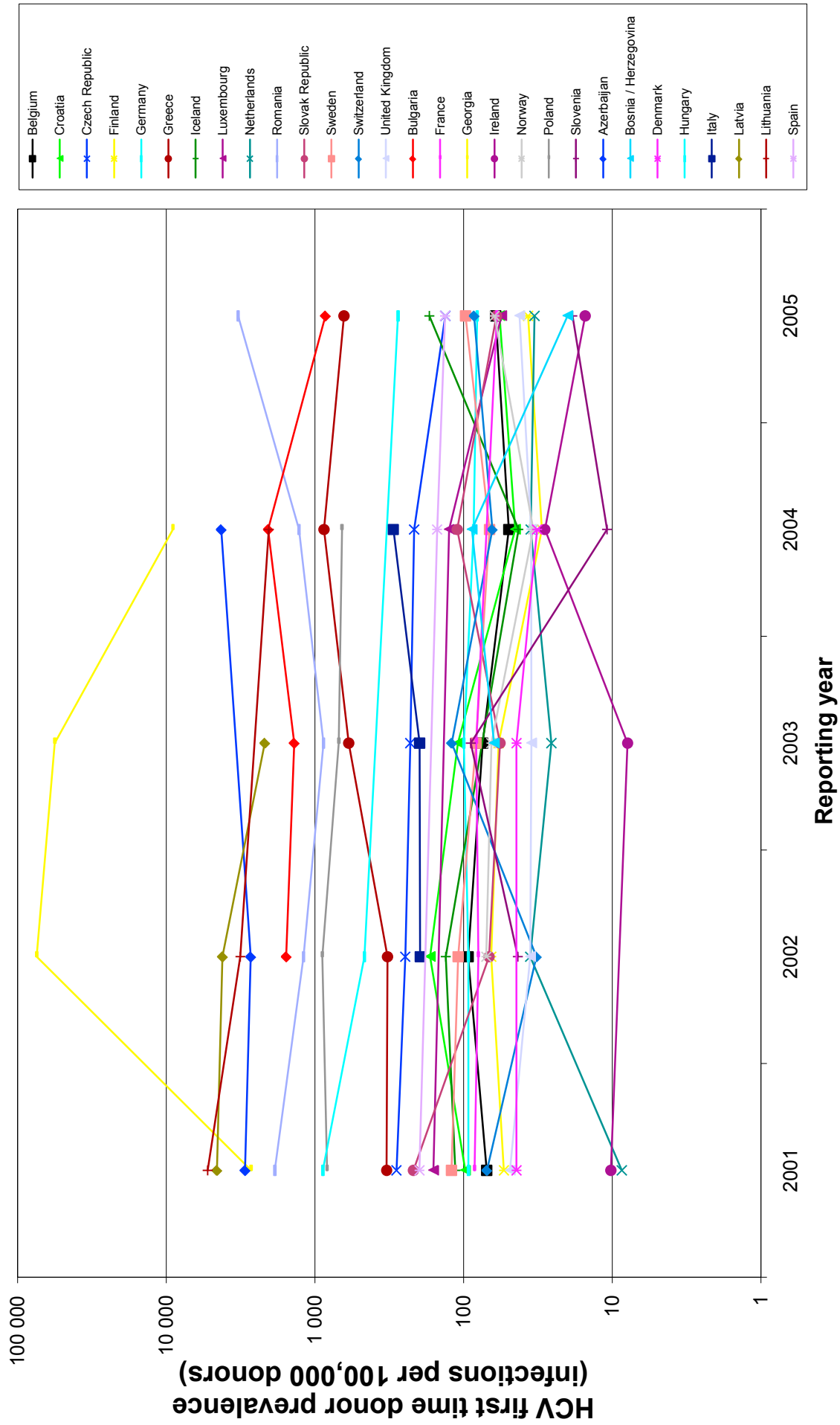


3.21: There are 6 out of the 21 countries with four or more entries that show a significant trend. Of these six there are four upward and two downward trends (Greece(+), Netherlands(+), United Kingdom(+), Ireland(+), Bulgaria(-), Poland(-)). There is no statistically significant general trend in first time donor HBV prevalence.

3.22. HCV FIRST TIME DONOR PREVALENCE

Country	Year					Trend
	2001	2002	2003	2004	2005	
Belgium	69.78	93.01	74.35	49.53	60.71	-
Croatia	97.44	168.1	109.1	44.92	57.23	-
Czech Republic	282.5	246.5	228.2	215.0	132.5	-5%
Finland	53.46	65.03	58.07	29.66	36.76	-
Germany	92.61	92.61	99.46	85.42	80.96	-
Greece	328.9	324.7	591.3	868.0	636.3	-
Iceland	113.51	131.49	0.00	42.68	169.5	-
Luxembourg	159.2	0.00	0.00	124.8	55.49	-
Netherlands	8.62	35.55	25.65	35.29	33.32	-
Romania	1,858	1,191	873.7	1,279	3,282	-
Slovak Republic	217.2	67.36	56.74	110.3	59.99	-
Sweden	120.4	108.5	82.51	66.80	96.94	-
Switzerland	69.67	32.31	120.1	64.01	84.75	-
United Kingdom	48.66	35.59	34.96	35.05	42.00	-
Bulgaria		1,559	1,377	2,060	849.5	-
France	84.29	79.39	81.98		59.60	-
Georgia	2,683	74,200	56,100	9,000		-
Ireland	10.20		7.87	28.36	15.18	-
Norway		70.24	64.97	33.91	61.79	-
Poland	827.2	891.2	689.7	657.0		-
Slovenia		43.13	89.37	10.84	18.50	-
Azerbaijan	2,947	2,700		4,259		
Bosnia / Herzegovina			62.24	87.82	19.92	
Denmark	44.00		44.00	32.00		
Hungary	882.3	463.9			275.5	
Italy		195.6	197.3	296.4		
Latvia	4,561	4,180	2,170			
Lithuania	5,261	3,169		2,039		
Spain	197.7			150.5	133.1	
Armenia	2,924		1,872			
Austria		120.6		54.42		
Albania	509.4					
Andorra		0.00				
Estonia	1,880					
Former Yug. Rep. Macedonia			1,725.21			
Malta				34.82		
Moldova	15,395					
Montenegro					688.6	
Portugal	208.6					
Cyprus						
Liechtenstein						
Russian Federation						
San Marino						
Serbia and Montenegro						
Turkey						
Ukraine						

*Prevalence as the number of infections per 100,000 donors



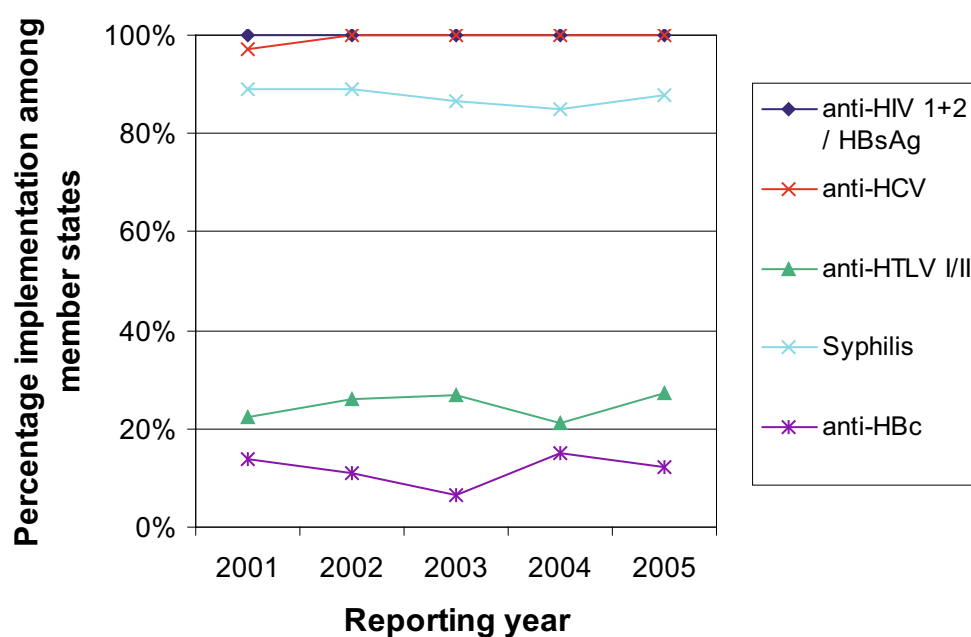
3.22: Out of the 21 countries with four or more entries there is only a significant downward trend in the Czech Republic (p-value 5%). However, there is a near statistically significant general trend of 0.025 log₁₀, which is equivalent to an annual relative decrease of 6% (95% CI -1%–12%).

3.23. SCREENING FOR INFECTIOUS AGENTS

In this section the implementation of various screening tests among MS is presented.

3.23.1. Serological testing

Below per reporting year the proportion of MS is shown that test all blood donations with the blood screening tests as indicated.

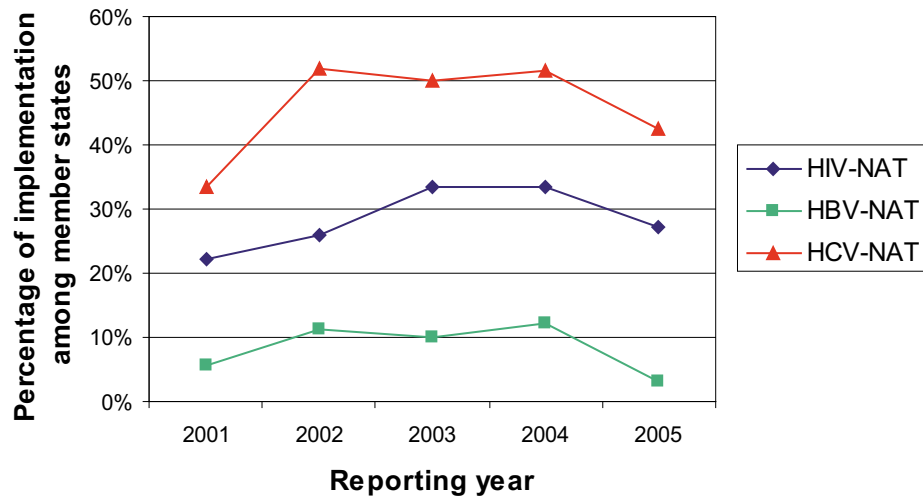


Reporting Year	Test*				
	anti-HIV 1+2 / HBsAg	anti-HCV	anti-HTLV I/II	Syphilis	anti-HBc
2001	100	97	22	89	14
2002	100	100	26	89	11
2003	100	100	27	87	7
2004	100	100	21	85	15
2005	100	100	27	88	12

* Expressed as % of blood donations tested (WB + components)

3.23.2. NAT testing

In the graph and table below the application of minipool-Nucleic Acid Amplification Techniques (NAT) testing on blood donations is given. The proportion of MS each year that have implemented screening of all blood donations with respective NAT tests is presented, excluding NAT screening by establishments for plasma fractionation.

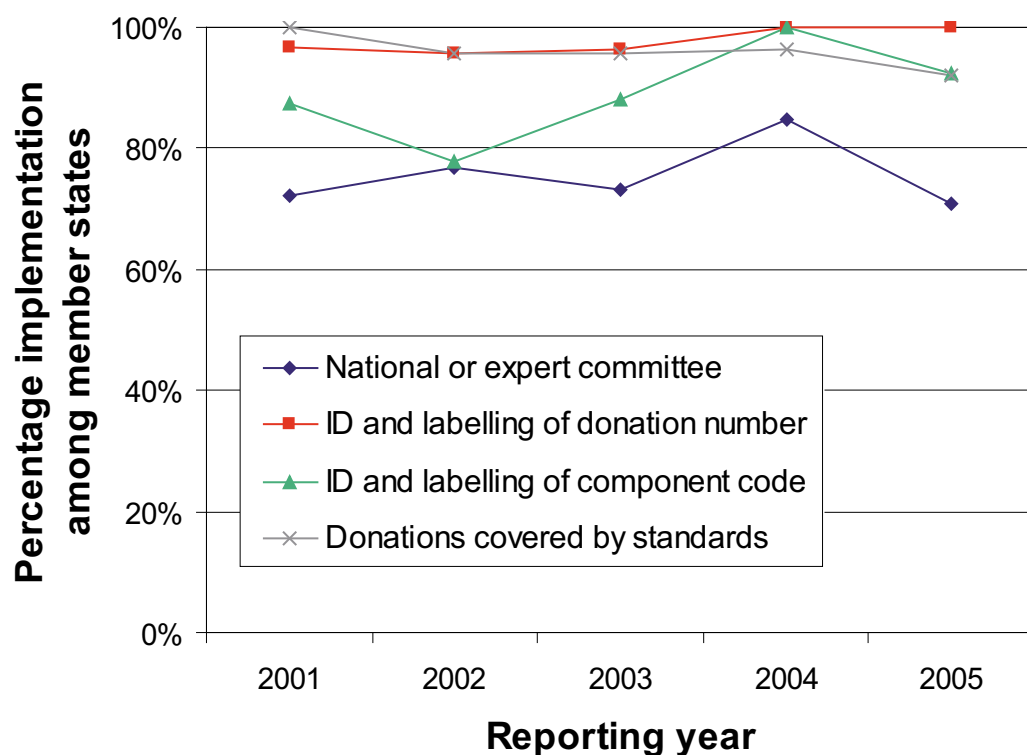


Reporting year	HIV-NAT*	HBV-NAT*	HCV-NAT*
2001	22	6	33
2002	26	11	52
2003	33	10	50
2004	33	12	52
2005	27	3	42

* Expressed in %

3.24. QUALITY ASSURANCE AND LABELLING

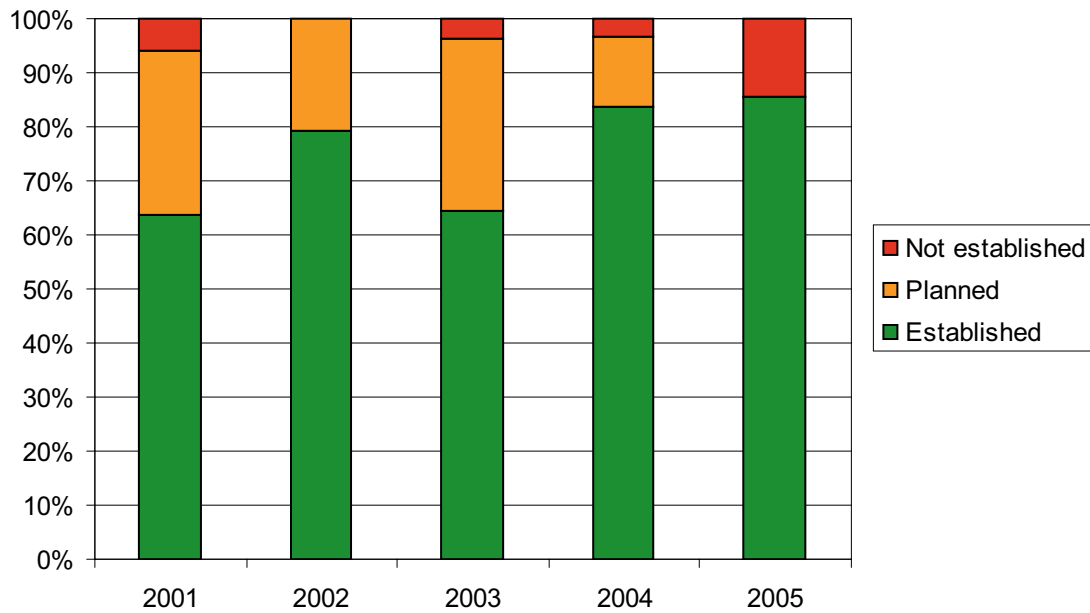
In this section the implementation of Quality Assurance (QA) or review programmes or application of various screening tests is presented. The proportion of MS each year that have implemented various programmes is shown.



Reporting year	National or expert committee*	ID and labelling of donation number*	ID and labelling of component code*	Donations covered by standards*
2001	72	97	88	100
2002	77	96	78	96
2003	73	96	88	96
2004	85	100	100	96
2005	71	100	92	92

* Expressed in %

In the figure and table below the status of implementation of quality systems is shown. The level of implementation or planned implementation amongst respondent MS each year is presented. There is a significant increasing trend (p-value 10%) on the percentage of established QS.



Reporting year	2001*	2002*	2003*	2004*	2005*	Trend
Established	64	79	64	84	86	10%
Planned	30	21	32	13	0	-
Not established	6	0	4	3	14	-

* Expressed in %

4. DISCUSSION, CONCLUSION AND FUTURE PLANS

The work presented here is a first attempt to obtain information on trends in the collection, testing and use of blood and blood components in Europe. The basis for the analysis is data provided by MS over the reporting period 2001-2005. Despite the relatively short reporting period, a number of observations can be made:

1. The proportion of reporting countries seems to have stabilised at around 72%. There is a constant base of reporting countries. This is a requirement for obtaining robust statistical estimates.
2. There is a stable blood supply as no trends are observed in the proportion of first time donors and in the number of donors and donations per inhabitant.
3. There is a (small) increase in the use of red blood cell units (0.4 per 1000 inhabitants).
4. There is a general decrease in WB use (25% per year). A clear downward trend is observed in those countries that in the beginning of the reporting period had a proportion of whole blood transfusions in the order of a few percent.
5. There is also a general decrease in the proportion of autologous blood transfusions (a relative decrease of 14% per year).
6. Even though there is no change in platelet usage, there is a small increase in the proportion of apheresis platelets use (a relative increase of 1.7% per year) .
7. There is a small increase in FFP units used (0.3 per 1000 inhabitants per year). However, there is no change in the ratio of FFP and RBC usage as both the FFP and RBC usage show similar increases.
8. There is no change in the amount of plasma obtained for fractionation nor is there a change in the amount of plasmapheresis plasma obtained.
9. There is a general increase in the proportion of leucocyte depleted RBCs. On average there is an increase of 4.3% per year. However, the rate of change differs strongly amongst MS.
10. There is a general increase in irradiation of RBCs (1% per year). The relative increase is estimated at 25% per year.
11. There is a general decrease in HBV infections amongst repeat donors (11% per year) and a general decrease in HCV infection amongst first time donors (6% per year).
12. There have been no substantial changes in screening regimens in the reporting period.
13. There is a statistically significant increase in the proportion of MS that have established implementation of a quality assurance system.

Analysis of the data obtained from the CoE Survey from subsequent years enables monitoring trends in the blood supply in Europe. It not only allows quantification of changes in the blood supply on a European level, which are known to MS at an individual level, it also allows comparison of trends amongst MS. Integration and reporting of data collected over a number of years may lead to new insights and facilitates additional means for data quality control.

Limitations and future plans

This report is the first to signal trends using data collected on the collection, testing, use and quality of blood and blood components by the CoE / EDQM. The limited time span of five years precludes rigorous statistical testing of trends in the collection, testing and use of blood and blood components in Europe. Some observations obtained from the surveys are likely to be erroneous. However, the data utilised have been previously approved and reported. By putting such data in historical perspective such errors become apparent. A constant, consistent and annually repeated baseline of reporting MS is a prerequisite for producing more robust statistical estimates. With the new web based survey which is used as of 2009 (reporting year 2007) and onwards, it is anticipated that compliance and quality of data will further increase. Also, processing of the data will be less error prone and it is expected that results may be reported with smaller lag times, depending on the submissions. Processing these data will undoubtedly result in a much more pronounced view on trends in Europe.

For future reports on trends a number of changes are anticipated. Since the appearance of the draft report statistical techniques were developed to specifically estimate the existence of trends in incidence rates (Janssen *et al.*, 2009). Also, the data show that trends may be contrasting in some cases, possibly due to regional differences. We will therefore try and integrate regional effects with nationally observed trends.

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