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Haemophilia care in Europe: a survey of 19 countries

B. O'MAHONY,* D. NOONE,* P. L. F. GIANGRANDE† and L. PRIHODOVA‡

*Irish Haemophilia Society, Cathedral Court, Dublin, Ireland; †Oxford Comprehensive Haemophilia Centre, Oxford, UK; and

‡Graduate School, Kosice Institute for Society and Health, Medical Faculty, PJ Safarik University, Kosice, Slovak Republic

Summary. In 2009, a questionnaire was circulated to 19 national haemophilia patient organizations in Europe affiliated to the European Haemophilia Consortium (EHC) and the World Federation of Hemophilia (WFH) to seek information about the organization of haemophilia care and treatment available at a national level. The responses received highlighted differences in the level of care despite the recent promulgation of consensus guidelines designed to standardize the care of

haemophilia throughout the continent of Europe. There was a wide range in factor VIII consumption with usage ranging from 0.38 IU per capita in Romania to 8.7 IU per capita in Sweden (median: 3.6 IU per capita). Despite the specific inclusion of coagulation factor concentrate in the WHO list of essential medications, cryoprecipitate is still used in some eastern European countries.

Keywords: organisation, treatment, specialist care

Introduction

A document outlining the European principles of haemophilia care, drafted by an inter-disciplinary group of haemophilia physicians with input from key patient opinion leaders and clinical nurse specialists, was published in 2008 [1]. This document was subsequently endorsed by both the European Haemophilia Consortium (EHC) and the World Federation of Hemophilia (WFH) and was the subject of an official launch at the European Parliament in Brussels in January 2009.

The 10 basic requirements outlined in Colvin *et al.* [1] are:

1. Establishment of a central haemophilia organization in each country with supporting local group.
2. National Haemophilia patient registries.
3. A network of multidisciplinary comprehensive care centres and complementary haemophilia treatment centres.
4. Partnership of health care professionals and patients in the delivery of haemophilia care.
5. Safe and effective concentrates at optimum treatment levels.
6. Home treatment and delivery.

7. Prophylaxis.

8. Specialist services and emergency care.

9. Management of inhibitors.

10. Encouragement of education and research.

A survey was planned to determine the extent to which these requirements of haemophilia care already applied in the various countries within Europe. The results could then serve as a baseline to monitor progress in subsequent years.

The continent of Europe is a disparate one with a wide range of GDP [2] and health systems in individual countries. There are currently 27 member states of the European Union (EU), which now include 10 countries of the former communist eastern bloc. The coming decades are likely to see further expansion of the EU to incorporate other countries such as Croatia, the Former Yugoslav Republic of Macedonia and Turkey. Several other countries in the region such as Switzerland, Norway and Iceland have no plans to join the EU but already have various trade and other bilateral agreements with the EU in place.

Methods

Between February and August 2009, a questionnaire was developed and sent out to the 43 national haemophilia patient organizations affiliated to the EHC in all European countries. Responses were received from 19 countries. The national haemophilia organizations that responded were not asked to specify the sources of their data but typically they would have consulted clinicians

Correspondence: Brian O'Mahony, Irish Haemophilia Society, Cathedral Court, New Street, Dublin 8, Ireland.
Tel.: +353 1 657 9900; fax: +353 1 657 9901;
e-mail: brian@haemophilia.ie

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and the national registry, where one exists, in addition to their own records (Table 1). The questionnaire was based on examining the extent to which the European principles of care reflect the reality of haemophilia care in these countries. The questionnaire consisted of 31 questions covering aspects of the 10 basic requirements for haemophilia care. The countries that responded included 16 member states of the EU and three non-EU countries (Russia, Bosnia-Herzegovina and Switzerland). The 19 countries covered a total of 28 916 patients with haemophilia A, 5545 patients with haemophilia B and 17 396 patients with von Willebrand disease.

Results

Organization of patient care and national patient registries

Thirteen of the 19 countries stated that they have a central organization for haemophilia care while six do not (Table 2). A total of 15 countries have national patient registries and four countries do not have a registry. The countries that do not yet have a registry are Latvia, Poland, Sweden and the Netherlands. In Sweden and Netherlands, each hospital maintains a separate registry but there is no national registry. In terms of management of the registry, in six countries the national organization is involved, in three countries the government is involved, in six countries clinicians are involved and in seven countries the national haemophilia patient organization is involved. Five countries have more than one organization involved in the registry. These countries are Romania, Russia, Slovakia, Hungary and Germany.

Table 1. Countries responding and not responding to the survey.

Countries that responded		Countries that did not respond	
EU	Non-EU	EU	Non-EU
Belgium	Russia	Austria	Albania
Bulgaria	Switzerland	Cyprus	Armenia
Czech Republic	Bosnia-Herzegovina	Denmark	Azerbaijan
France		Estonia	Belarus
Germany		Finland	Croatia
Hungary		Greece	Georgia
Ireland		Italy	Iceland
Lithuania		Luxembourg	Israel
Latvia		Spain	Macedonia
Netherlands			Moldova
Poland			Norway
Portugal			Serbia
Romania			Slovenia
Slovak Republic			Turkey
Sweden			Ukraine
United Kingdom			

Fifteen of the 19 countries reported that they have comprehensive care centres (CCC's). Those countries that state that they do not have CCC's are Bosnia-Herzegovina, Bulgaria, Portugal and Hungary. A total of 16 countries stated that they have haemophilia treatment centres (HTC's). Those that state they do not have HTC's are Bosnia-Herzegovina (where no centre is officially recognized yet by the government), Russia and Sweden (in both Russia and Sweden all centres are categorized as CCC's).

In relation to partnership in the delivery of haemophilia care, countries were asked who has a significant role in relation to national decision making on haemophilia care and also who has a role in the choice of treatment products for haemophilia (Fig. 1). In relation to the decision making on haemophilia care nationally, four countries (Romania, Lithuania, Russia and Sweden) stated that the government played a significant role. A total of 16 countries stated that the health ministry played a significant role, three countries (France, UK and Ireland) stated that the hospitals played a significant role, nine countries stated that the national haemophilia patient organization played a significant role and 15 countries stated that clinicians played a significant role. In the majority of countries, the clinicians, the health ministry and the patient organization were those who played a significant role in the decision making.

In relation to choice of haemophilia treatment products (Fig. 1), 12 countries stated that the health ministry were involved with the choice, one country (Sweden) stated that the regional government were involved, hospitals were involved in eight countries, patients in four countries, the national haemophilia patient organization in three countries (Portugal, France and Germany), Clinicians in eight countries and a national

Table 2. List of Countries with a central organization for haemophilia care.

Country	Has a central organization for haemophilia care
Romania	Yes
Bosnia-Herzegovina	No
Bulgaria	No
Lithuania	Yes
Latvia	Yes
Portugal	No
Russia	Yes
Switzerland	No
Poland	Yes
Slovakia	Yes
Belgium	Yes
France	Yes
Hungary	Yes
United Kingdom	Yes
Ireland	Yes
Germany	No
Sweden	No
Czech Republic	Yes
Netherlands	Yes

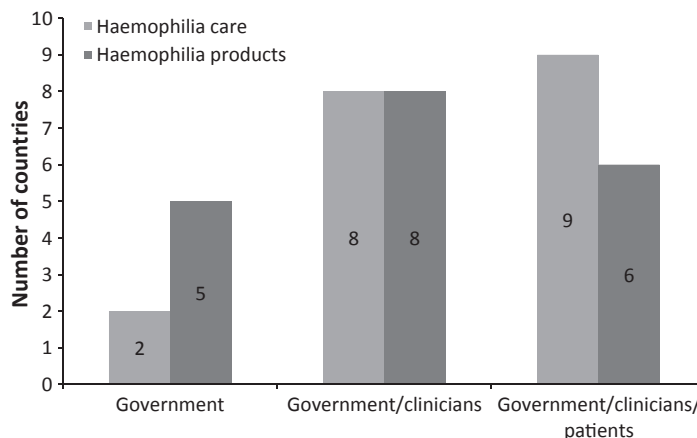


Fig. 1. Summary of groups involved in decision making on haemophilia care and products.

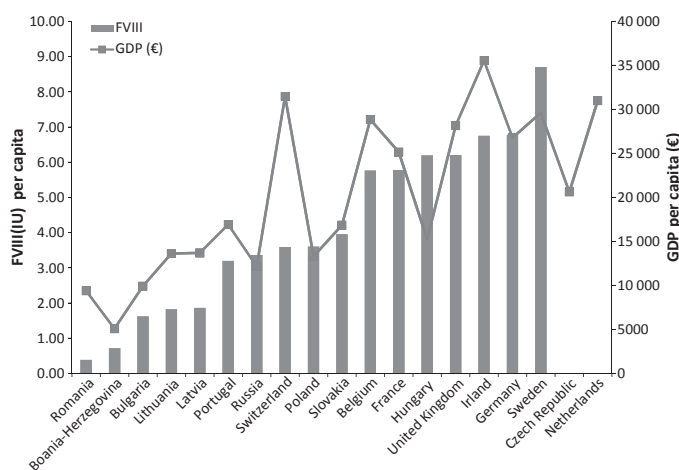


Fig. 2. Comparison of GDP per capita (€) and factor VIII per capita use.

procurement committee in three countries (Bosnia-Herzegovina, Hungary and Ireland). In the case of Ireland, the patient organization is fully involved in the decision making as they have a formal role in the national procurement committee for factor concentrates. Ireland has a Haemophilia Product Selection and Monitoring Advisory Board which recommends all the products to be purchased on a national basis for Haemophilia, von Willebrands disease and rare bleeding disorders. The board sets the selection criteria, evaluates the products against these criteria and recommends the products to be purchased, the quantities to be purchased and the duration of each tender. The Board includes the three clinicians who are directors of the three comprehensive haemophilia treatment centres and two representatives from the national haemophilia patient organization [3]. In the procurement committees in Hungary and Bosnia-Herzegovina, the national patient organizations are invited as observers but do not have a formal role in the process of product selection.

Availability of safe and effective concentrates at optimum treatment levels

The survey revealed enormous variation in relation to the availability of factor concentrates in the European countries surveyed (Fig. 2). The country with highest per capita use was Sweden while consumption was lowest in Romania. A total of 17 countries reported figures for their factor VIII (FVIII) per capita use for 2009, which ranged from 0.38 to 8.7 IU per capita (median was 3.6 IU per capita; mean was 4.1 IU per capita, standard deviation was 2.4 IU per capita). Two countries (Romania and Bosnia-Herzegovina) reported a usage of <1 IU per capita whereas three countries (Bulgaria, Lithuania and Latvia) use <2 IU per capita. There was a clear correlation between per capita factor consumption and GDP per capita among the countries surveyed.

If we use GDP per capita as a crude measure of economic strength, it is interesting to note that all five of the eastern European countries that use <2 IU per capita

Table 3. Breakdown of patient access to treatment in European countries.

Country	GDP per capita(€)	Access to home treatment	Access Prophylaxis treatment	Children currently on Prophylaxis (<18 years)	Adults currently on Prophylaxis (≥18 years)	Access to ITT
Belgium	28 846	51–75%	Yes to all	76–100%	51–75%	76–99%
Bosnia-Herzegovina	5077	None	Yes for some	1–25%	None	None
Bulgaria	9 923	10–50%	Yes for some	26–50%	None	None
Czech Republic	20 615	76–100%	Yes to all	76–100%	1–25%	100%
France	25 154	76–100%	Yes to all	51–75%	1–25%	100%
Germany	26 769	76–100%	Yes to all	76–100%	26–50%	76–99%
Hungary	15 231	Unknown	Yes to all	76–100%	76–100%	100%
Ireland	35 538	76–100%	Yes to all	76–100%	26–50%	100%
Latvia	13 692	51–75%	Yes to children	1–25%	None	100%
Lithuania	13 615	76–100%	Yes for some	None	None	None
Netherlands	31 000	76–100%	Yes to all	76–100%	76–100%	100%
Poland	13 308	51–75%	Yes to children	51–75%	None	None
Portugal	16 923	51–75%	Yes to children	76–100%	1–25%	<10%
Romania	9 385	None	Yes for some	1–25%	None	None
Russia	12 154	51–75%	Yes for some	51–75%	26–50%	10–25%
Slovakia	16 846	76–100%	Yes to children	51–75%	1–25%	100%
Sweden	29 615	76–100%	Yes to all	76–100%	76–100%	100%
Switzerland	31 462	51–75%	Yes for some	76–100%	26–50%	100%
United Kingdom	28 154	51–75%	Yes to children	76–100%	1–25%	76–99%

significantly under perform in relation to their FVIII per capita usage, given their relative economic strength. Of the western European countries, the consumption of FVIII in Portugal and Switzerland was less than that which might be predicted by overall GDP values. In the case of Ireland, the very rapid increase in GDP per capita over the previous 5 years has outstripped the high increase in per capita FVIII use (which increased from 1.9 IU per capita in 1997 to 6.75 IU per capita in 2009). Only Hungary and Sweden outperform in relation to their IU per capita FVIII use when compared with their GDP per capita. Sweden has been the pioneer in the use of prophylactic therapy for haemophilia and prophylactic therapy has been used in Sweden for the past 30 years.

Home treatment and prophylaxis

Home treatment is available in 17 of the 19 countries surveyed and is delivered directly to the patients' home in six of the countries (Table 3). Home treatment is not available in Bosnia-Herzegovina and Romania. It is available to 75–100% in eight countries (Slovakia, Czech Republic, Lithuania, The Netherlands, France, Germany, Ireland and Sweden) and available to 50–75% of persons with haemophilia in another seven countries. Not surprisingly, the two countries where home treatment is not available are the same ones which consume <1 IU per capita of FVIII.

Prophylaxis is theoretically available to all persons with haemophilia in eight countries and available to some children in five countries. However, prophylaxis is limited or even unavailable in six countries. Prophylaxis is available to children with severe haemophilia in 10 countries to the extent that, 75–100% of children use prophylaxis (Belgium, Czech Republic, Hungary,

Switzerland, The Netherlands, Portugal, UK, Germany, Ireland and Sweden). Prophylaxis is available to 50–75% of children with haemophilia in a further four countries (Poland, Russia, Slovakia and France). There is limited or no availability in Bosnia-Herzegovina, Bulgaria, Latvia, Lithuania and Romania.

Adults with severe haemophilia have wide availability of prophylaxis in three countries (Hungary, The Netherlands and Sweden) and prophylaxis is available to upto 50% of adults with Haemophilia (probably on a case by case basis) in a further six countries (Russia, France, Portugal, UK, Germany and Ireland) (Table 2).

Specialist care

In relation to the elements of comprehensive care, countries were asked the degree of access they have to various elements of comprehensive care. This included access to emergency medicine and acute surgery, paediatrics, infectious disease specialists, hepatology, rheumatology, orthopaedics, physiotherapy, dentistry, obstetrics and gynaecology, genetics, social and psychosocial support, pain management, general surgery and urology (Table 4). Seven countries (Belgium, France, Germany, Ireland, Latvia, Lithuania and Romania) stated in their replies that they had access to all of these services at all times. It is difficult to accept that there would be a high standard of availability to all the specialities of comprehensive care in countries such as Romania, which has such a low per capita use of factor concentrate and no availability of home treatment or prophylaxis.

The major disparities between countries in relation to access to comprehensive care seem to be in relation to access to infectious diseases specialists (three countries), Haepatology (four countries), Rheumatology (four coun-

Table 4. Access to specialist care for people with bleeding disorders in 19 European countries.

Country	Emergency medicine and acute surgery		Infectious disease specialists (HIV)		Hepatology		Rheumatology		Orthopaedics		Physiotherapy		Dentistry		Obstetrics and gynaecology		Genetics		Social and psychological support		Pain management		General surgery		Urology	
	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Belgium	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Bosnia-Herzegovina	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Bulgaria	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Czech Republic	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
France	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Germany	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Hungary	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Ireland	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Latvia	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Lithuania	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Netherlands	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Poland	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Portugal	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Romania	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Russia	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Slovakia	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Sweden	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
Switzerland	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown
United Kingdom	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown	Always	Unknown

tries), Orthopaedics (three countries), Physiotherapy (five countries) and surprisingly Dentistry (five countries). Genetics was not available in eight countries and social and psychosocial support was not available in 11 of the 19 countries. Pain management was not available in 10 countries. Urology was not available in 11 countries. Clearly there is a major divergence in relation to access to the different specialities, which are either a core part of or augment the comprehensive care team.

Immune tolerance for patients with inhibitors

Five countries (Bosnia-Herzegovina, Bulgaria, Lithuania, Poland and Romania) reported that immune tolerance therapy is not available at all. Immune tolerance is available for some patients in Russia. Immune tolerance is available in all the other countries surveyed when required.

Provision of safe and effective treatment

In relation to the use of factor concentrates (Table 5), 10 countries stated that recombinant factor concentrates were always available with plasma-derived concentrates being rarely available; 13 countries stated that plasma-derived concentrates were always available but that recombinant factor concentrates were rarely available. Four Countries (Romania, Bosnia-Herzegovina, Lithuania and Russia) reported persisting but occasional use of cryoprecipitate. Romania is the only country that state they use fresh plasma exclusively, although it is also used infrequently in Bosnia-Herzegovina, Lithuania and Russia.

Recombinant concentrates were recorded as always available in all the countries which reported a FVIII consumption of 5 IU per capita or more. The countries where recombinant factor concentrates are the primary products used are Ireland, Sweden, France, Switzerland and the United Kingdom. Plasma-derived concentrates are the principal products employed in Bosnia-Herzegovina, Bulgaria, Lithuania, Latvia, Russia, Poland, Slovakia and Hungary.

Discussion

The survey revealed significant variation in relation to the organization of haemophilia care and availability of factor concentrates in the European countries surveyed. These findings are not, of course, entirely unexpected but they will serve as important baseline data to monitor progress over the coming years. It is also worth specifically noting the very dramatic improvements in access to treatment products in Russia and Poland in recent years. The government in Poland has improved access to factor concentrates to the extent that they are now at the median use of 3.6 IU per capita in Europe.

Table 5. Breakdown of access to treatments for bleeding disorders in European countries.

Country	Haemophilia				Von Willebrand disease (vWD)			
	Plasma	Cryoprecipitate	Plasma-derived Factor Concentrate	Recombinant Factor Concentrate	Plasma	Cryoprecipitate	Plasma-derived Factor Concentrate	DDAVP
Belgium	Never	Never	Rarely	Always	Never	Never	Always	Always
Bosnia-Herzegovina	Rarely	Rarely	Always	Rarely	Never	Never	Always	Never
Bulgaria	Never	Never	Always	Rarely	Never	Never	Always	Never
Czech Republic	Never	Never	Always	Rarely	Never	Never	Always	Rarely
France	Never	Never	Always	Always	Never	Never	Always	Always
Germany	Never	Never	Always	Always	Never	Never	Always	Always
Hungary	Never	Never	Always	Always	Never	Never	Always	Rarely
Ireland	Never	Never	Never	Always	Never	Never	Always	Always
Latvia	Never	Never	Always	Never	Never	Never	Always	Always
Lithuania	Rarely	Rarely	Always	Rarely	Rarely	Rarely	Rarely	Always
Netherlands	Rarely	Never	Always	Always	Rarely	Never	Rarely	Always
Poland	Never	Never	Always	Never	Never	Never	Always	Never
Portugal	Never	Never	Always	Always	Never	Never	Always	Always
Romania	Always	Rarely	Rarely	Rarely	Rarely	Rarely	Rarely	Rarely
Russia	Rarely	Rarely	Always	Rarely	Rarely	Rarely	Always	Never
Slovakia	Never	Never	Always	Rarely	Never	Never	Always	Rarely
Sweden	Never	Never	Rarely	Always	Never	Never	Always	Always
Switzerland	Never	Never	Rarely	Always	Unknown	Unknown	Unknown	Unknown
United Kingdom	Never	Never	Rarely	Always	Never	Never	Always	Rarely

The improvement in Russia has been even more remarkable. In 2004, Russia was using <0.3 IU per capita and by 2009 this had increased to 3.36 IU per capita. This is attributed to the inclusion of factor concentrates in the federal budget and to the extremely hard work of the Russian national patient organization and clinicians over many years.

Political support will be required to continue to develop haemophilia care in Europe and it is gratifying that the EHC launch of the European principles of care was hosted by the European parliament in January 2009 and attended by several Members of the European Parliament (MEP's). A meeting to promote optimal use of blood products under the aegis of the European commission in 1999 [4] made a number of recommendations which were precursors to the recent principles [1]. A follow-up meeting was held a decade later to monitor progress and a key recommendation is that the minimum national level of FVIII concentrate which should be used is 2 IU per capita (P. Giangrande and B. O'Mahony, Personal Communication).

Concerted efforts to supplant the use of cryoprecipitate for the treatment of haemophilia with good-

quality concentrates should perhaps be considered to be the first priority for implementation. The World Health Organisation (WHO) reaffirmed the inclusion of coagulation factor concentrates in the list of essential medications in 2005 [5], while also specifically making the point that cryoprecipitate is inherently less safe.

Official optimum treatment levels have not yet been defined, although the WFH in the past has stated that a minimum level of 1 IU of FVIII per capita is required in countries for basic treatment and survival [6].

It is clear that there will be a continuing demand in Europe for both recombinant and plasma-derived concentrates for many years to come. Concentrate consumption has been shown to increase in line with economic development [7] and thus usage is likely to continue to grow significantly in the coming years.

Disclosures

The authors stated that they had no interests which might be perceived as posing a conflict or bias.

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