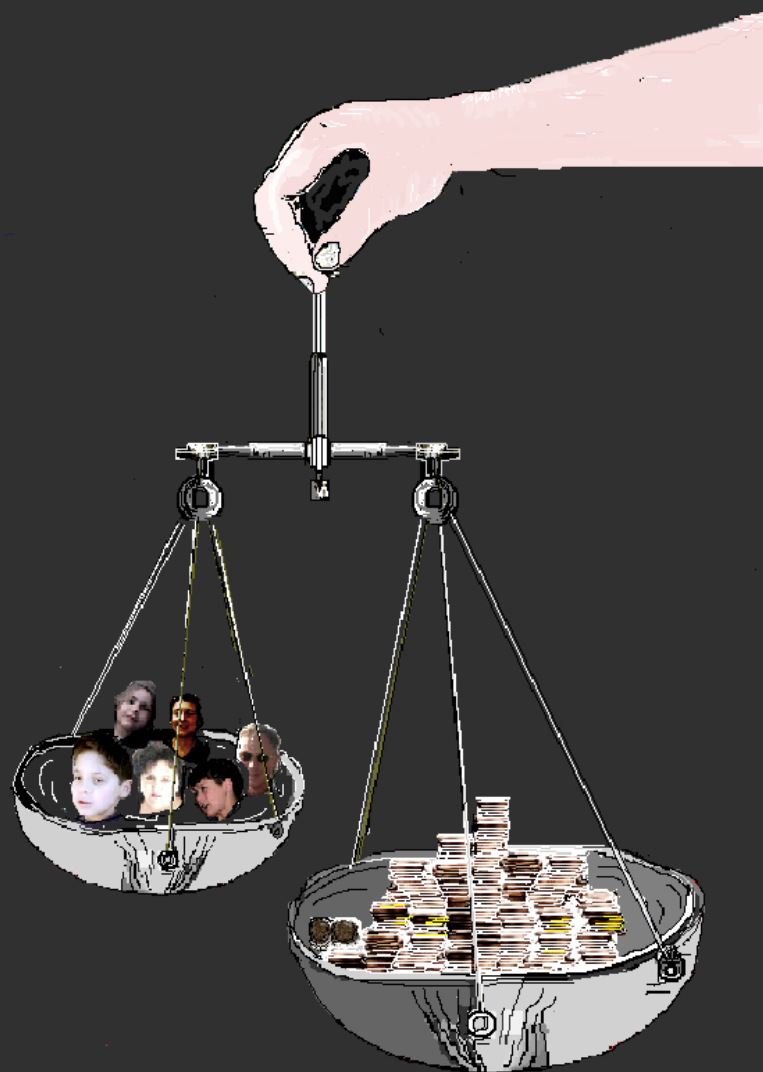


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Patients' rights: getting the perfect balance



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Patients' rights: the need for legislation



This section of the report looks at the groundswell of opinion on the subject of patient rights, and:

- Ω Examines why the increasing mobility of patients across national borders has brought the topic of patients' rights to the attention of various EU agencies.
- Ω Analyses the impact of data on the health inequities that exist across Europe, noting how these data are provoking patient-led campaigns for more uniform standards and for excellence of healthcare pan-EU (including an officially-blessed European Patients' Rights Day).
- Ω Describes international initiatives that attempt, but largely fail, to tackle the issue of patients' rights.

Why patients' rights?

On April 18th 2008, some 120 patient representatives, healthcare providers and administrators, politicians, religious leaders and members of the legal profession from more than 20 countries gathered in the northern Italian town of Gorizia. The meeting was hosted by Rome-based Active Citizenship Network (ACN), the international offshoot of Cittadinanzattiva, a large Italian civic movement. The participants had come to talk about one subject: improving the rights of patients across Europe.

Perhaps the most important fact about this conference, entitled 'European Patients' Rights: a European and National Challenge', was that it received the full blessing of the European Commission, the European Parliament, and the European Economic and Social Committee (EESC). All these institutions now acknowledge the need for some sort of framework to address the subject of patients' rights.

A pan-European event

ACN's Gorizia conference was just one of many international celebrations that the organisation was orchestrating throughout Europe in celebration of the 2nd European Patients' Rights Day. Patients and leading political and

healthcare figures from places as far apart as Ukraine in the east to Ireland in the west undertook high-profile activities to raise awareness of the importance of protecting and upholding patients' rights.

A personal endorsement from the European Commissioner for Health

Mrs Androula Vassiliou, then eight days into her new job as European Commissioner for Health, sent the Gorizia conference the following message:

"There are common elements of patients' rights shared by most EU health systems. These include providing timely and appropriate healthcare, sufficient information to patients about the different treatment options, respecting confidentiality of health data, and compensation for harm from negligence in healthcare care. However, the mechanisms to implement these principles vary widely between Member States. Moreover, such mechanisms may not sufficiently take into account the situation of patients in other Member States.

For all these reasons, the initiative taken by Active Citizenship Network is useful and most welcome."

ACN has taken just seven years of campaigning to reach this point. ACN's efforts may be remarkable, but they also show the high level of importance people and patients attach to the subject of patients' rights.

At Gorizia

The venue, Gorizia, was chosen for good reason: to illustrate the potential of healthcare services when delivered across borders. The town sits on the Italian side of the border with Slovenia.



Gorizia's hospital functions in tandem with its counterpart in Slovenia's Nova Gorica. Some healthcare services are shared among Italian and

Differences in health among Italians and Slovenians

	Italy	Slovenia
Life expectancy at birth, 2006	80.4	77.8
Infant mortality, 2005 per 1,000 live births	4.7	4.1
Rates of hospital discharge from cardiovascular disease, 2003 per 100,000	2,444	1,745
Estimated prevalence of diabetes, 2003 among population aged 20-79 [crude %]	6.6	9.6

Sources: OECD, EHN

Slovenian inhabitants. Representatives from the two 'towns' were present at the April 18th meeting to talk about their novel healthcare partnership.

Slovenia holds the Presidency of the European Union for the first half of 2008, and has made a commitment to improve co-operation between Member States on health issues, particularly in the area of cross-border care.

Such cross-border relationships are just one reason why patients' rights are becoming a topical and important issue at local, national, and EU levels. As patients travel more widely for their healthcare needs, they require assurances that

healthcare standards are at least adequate (and, preferably, high quality), and are available Europe-wide.

Forces favouring patients' rights

The experiences of patients within the national health services of Europe varies from EU Member State to State (and even between localities within individual countries)—sometimes resulting in disturbing differences in both life expectancy and quality of life among EU citizens. Thus, while the life expectancy of Italians is marginally higher than Slovenians, infant mortality rates in Italy are above those in Slovenia. And whereas levels of

Healthcare cooperation in Gorizia/Nova Gorica

Mirko Brulc, Mayor of Nova Gorica, Slovenia, told the conference that the healthcare systems of Gorizia and Nova Gorica share a number of contracts that aim to improve the situation of patients—whether these patients are Italian or Slovenian. The hospitals of the twin towns are just 100 metres apart, and partner facilities such as ultrasound (which, he added, will soon also be deployed for breast cancer screening). Mr Brulc emphasised that the rights of patients should be promoted, particularly as the public is not always aware of these rights.

cardiovascular disease are higher in Italy than in Slovenia, the prevalence of diabetes in Slovenia tops that of Italy.

Money, in part, explains the variance in patients' encounters with healthcare systems (and their health outcomes). With growing financial pressures being placed on healthcare systems by ageing, chronically-ill populations, governments have been forced to ration the supply of medical care and treatment—a response that is widening the health inequities across the EU.

Melody Ross, ACN Project Manager, explained to the meeting that the current nationally-based legislative

framework protecting citizens' human rights does not tackle the issues of equitable healthcare. "Even though it is necessary to recognise that policymakers are working with increasing financial constraints," she said, "more attention must to be paid to citizens as patients, who should have a say on the level of health protection they want".

In addition to increasing patient mobility and the budgetary constraints placed by governments on healthcare, other factors are forcing a debate on patients' rights. Healthcare topics such as hospital infections, influenza pandemics, and obesity have moved into the political spotlight. International organisations, such as the World Health Organization and the EU, are charging national governments with the responsibility to keep these global health threats at bay.

For these reasons, ACN believes that it has a case to take the issue of patients' rights to the highest echelons of the European Commission, and to press for appropriate legislation to enforce patients' rights—and gain official recognition of European Patients' Rights Day.



The European Commission and patients' rights

“As regards European Community actions in the field of healthcare: I am committed to ensure that they take citizens' and patients' rights as a key starting point.”

Mrs Androula Vassiliou
EU Commissioner for Health

‘Convention on Human Rights and Biomedicine’, and the European Parliament’s 2000 ‘Charter of Fundamental Rights of the European Union’, article 35 of which calls for “a high level of human health protection”.

The situation in Europe

Herman Nys, Director of the Centre for Biomedical Ethics and Law (CBMER) at the Katholieke Universiteit, Leuven, Belgium, has made the study of patients' rights his career.

Professor Nys did not attend the Gorizia conference, but has talked at other venues about the differing levels of legal protection provided to patients across Europe.

He notes that Belgium, Cyprus, Finland, France, the Netherlands and Spain have all passed legislation to uphold patients' rights. Patients' rights in Denmark and Sweden are incorporated into more general laws regulating healthcare. Germany has no patients' rights legislation (though it does operate a binding Patient Charter).

The situation across Europe is further confused by the fact that these various charters and laws can be policed at national and/or regional levels—causing disparities in healthcare services, even within a single country.

International initiatives

International bodies have made several, mainly- unsuccessful, efforts to promote the notion of patients' rights. A 1994 meeting run by the World Health Organization (WHO) Regional Office for Europe produced a ‘Declaration on the Promotion of Patients' Rights in Europe’. Although the Declaration raised the profile of the issue, it is not legally binding. The same restriction is true of the Council of Europe’s 1997

Certainly, the EU has limited responsibilities in health and health policy. Article 152 of the 2002 EU Treaty allows the EU to legislate only on issues of blood safety, organs, products of human origin, and phytosanitary and veterinary health. Furthermore, patient mobility is not even mentioned in the EU Treaty, even though the legal basis of cross-border care was recognised as long ago as 1971 with the introduction of the so-called E111 scheme enabling EU citizens to get treatment abroad, funded by their home country. Later, in 2004, migrant workers were given the right to access healthcare in the country in which they were working.

EU influence on healthcare, however, has been gradually increasing since the European Court of Justice established in 1984, through case law, the right of

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What happened on European Patients' Rights Day



Austria: translation of European Charter of Patients' Rights into German and Slovak.

Bulgaria: press conference, posters and leaflets distributed in Sofia.

Czech Republic: translation of the Charter; leaflets distributed.

Cyprus: conference in Limassol with representation from politicians and healthcare providers.

Estonia: petition; raising media awareness; posters and leaflets distributed.

France: meeting with the President of the Commission of Medical and Social Affairs in the national Parliament; distribution of posters; raising media awareness; video; personnel in 40 hospitals wearing badges supporting the Day.

Germany: press conference in Berlin; leaflets distributed.

Greece: posters and leaflets distributed; seminar in Athens celebrating the inauguration of a patients' ombudsman in all hospitals; speeches in medical universities; raising media awareness; creating a coalition of 10-15 consumer groups.

Hungary: translation of the Charter; raising media awareness; leaflets distributed to all four facilities of medicine to elicit support from doctors.

Ireland: week-long activities, including raising media awareness; distribution of leaflets about patients' right of access to healthcare; meetings with main opposition party.

Italy: stands set up in public places throughout the country; Gorizia conference.

Romania: meetings with patients, providers and the media in Brasov, Bucharest, and Carei to raise awareness about patients' rights; distribution of literature on the Charter and on European Patients' Rights Day.

Netherlands: raising media awareness; translation of the Charter; its distribution to 5,000 contacts across the country.

Slovakia: leaflets distributed; raising media awareness; national conference in Bratislava.

Slovenia: partnership with Active Citizenship Network to organise the Gorizia conference.

Spain: raising media awareness; assembly of a patients' jury to consider whether patients' associations are actors or spectators on European patients' rights issues.

Sweden: translation of the Charter, distribution of leaflets about the Gorizia conference.

Switzerland: Swiss pharmaceutical company Roche distributed buttons about the Charter to all its employees, placed displays in the workplace, and broadcasted information about the Charter on its website.

Turkey: raising awareness among the media; production of a radio programme: 'I am a patient, and I have rights'.

UK: distribution of leaflets and posters about the Charter at the University Hospital, Leicester.

Ukraine: raising media awareness; meetings with Ministry of Health; roundtable for patients and health professionals; sponsored walk.

Lithuania: translation of the Charter; raising media awareness by printing a leaflet in *Lietuvos Sveikata* [Lithuanian Health], which is distributed nationwide.

Latvia: working with the Ministry of Health; translation of the Charter; leaflets distributed; competition for the most patient-friendly environment; conference.

Macedonia: conference opened by the Minister of Health; promotion of books about the rights of people with mental health problems; distribution of posters and leaflets about patients' rights under Macedonian law.

Malta: seminar; raising awareness in the media; leaflets distributed.

Poland: seminars and workshops directed at over 60 Polish patient groups; conference with patient groups from neighbouring countries; translation of the Charter; launch of new campaign, 'Patients' Rights—My Rights'.

Organisations around Europe that participated in European Patients' Rights Day, April 18th 2008

Austria	International Neurotrauma Research Organization
Bulgaria	The Bulgarian Association for Patient's Rights Defense. The Index Foundation. Women without Osteoporosis.
Cyprus	The European Social Forum of Cyprus.
Czech Republic	The Czech Association of Patients.
Estonia	Estonian Patients' Advocacy Association.
France	l'Assistance Publique des Hôpitaux de Paris. Collectif inter Associatif sur la Santé (CISS). Femmes pour Toujours.
Germany	Deutschen Gesellschaft für Versicherte und Patienten.
Greece	Consumers' Association of Kavala. Day Evropaiki Ekfrassi.
Hungary	Hungarian Civil Liberties Union.
Ireland	Adelaide Hospital Society.
Italy	Cittadinanzattiva.
Latvia	Sustento.
Lithuania	Vilnius University Children's Hospital.
Macedonia	CRPRC Studiorum. Ministry of Health of Macedonia.
Malta	Malta Health Network.
Netherlands	Zorgbelang Gelderland.
Poland	Institute for Patients' Rights and Health Education.
Romania	Sanhoep Romania.
Slovakia	Association for Patients' Rights.
Slovenia	Europa Donna.
Spain	Spanish Patient Forum.
Sweden	Prostate Cancer Association Sweden.
Switzerland	Roche.
Turkey	Association for the Right to Health.
UK	University Hospitals of Leicester.
Ukraine	Ukrainian Union of Patients' Organizations.

... Continued from page 8

European patients to access healthcare when abroad in another Member State. George Arestis, a judge at the European Court of Justice, observed at a roundtable discussion during the Gorizia conference that

“the progressive abolition of national borders, and the increased mobility of EU citizens, have raised expectations. European citizens now anticipate being afforded the same rights as others in neighbouring

Member States by virtue of the fact that they are living within the EU. That includes rights to healthcare. There is an unavoidable clash between the need to ensure an effective application of citizenship rights, and the

crude fact that it is still up to the Member States to pick up the bill. An appropriate balance needs to be achieved between the two conflicting concerns”, Judge Arestis argued. [A fuller account of the judge’s speech can be read on pages 19-26.]

Still some way to go

Charlotte Roffiaen, Director of ACN, pointed out that several aspects of patients’ rights have indirectly benefited from EU legislation. Other EU legislation—such as that concerning the protection of personal data, and efforts by the Commission to improve the transparency of institutions—guarantee patients certain levels of personal privacy, and enforce accountability among hospitals and other healthcare providers.

In the meantime, a proposed European Commission directive on cross-border care, which is scheduled to be published in July 2008, could attempt to legalise a process in which European nations’ healthcare systems respond to individual patients’ needs. The title and the text of the draft directive

refer to patients’ rights. The document mentions, in particular, two healthcare rights—the right to free choice, and the right to innovation. Pan-European networks would be developed to disseminate scientific and technological innovations, making the latter accessible to all EU citizens.

But despite evidence of clear progress on patients’ rights—and even if the cross-border directive does get published—Ms Roffiaen maintained that the scope of the latter only relates to circumstances when European patients (or health professionals) travel to another Member State to receive (or deliver) care. The directive therefore does not have any influence on the vast majority of patient experiences within their own country, on the list of medical treatments covered by the national healthcare systems, or on how much money governments are prepared to pay to ensure that patients receive high-quality care.

Ms Roffiaen wondered whether the directive would, in the end, backfire, and widen gaps between the poorest and richest Member

States. Only citizens of European countries with governments willing to underwrite generous coverage schemes for healthcare will be able to afford to travel abroad for care.

All of which explains why ACN is campaigning for legislation on patients’ rights Europe-wide.

Active Citizenship Network and patients' rights



This section of the report looks at the major role played by the Rome-based Active Citizenship Network (ACN) in galvanising a civic movement to fight for the institutionalization of patients' rights at EU and national level, and:

- Ω Profiles ACN and its short seven-year history in the field of patients rights.
- Ω Describes ACN's patients' rights campaign, from the drafting of a 14-point European Charter of Patients' Rights to engaging the European Commission.

H

ow ACN has influenced the agenda

Active Citizenship Network (ACN) has made rapid progress in getting patients' rights recognised as a distinct set of entitlements within the European legislative agenda. Though ACN knows that it still has more work to do, the network's achievements to date have been impressive.

Back in 2001, the civic movement Cittadinanzattiva gathered together European NGOs that focused on community engagement to help it launch an international offshoot, ACN. Today, that ACN network has grown to include 90 partner organisations located in 30 European countries.

ACN, like Cittadinanzattiva, promotes an understanding of democracy and democratic values (including the rights of consumers and patients), as well as an understanding of the role that citizens should and can perform within society. ACN's civic partners are also vigorous in evaluating national policies and practice.

ACN's Patients' Charter

To gain a consensus on the type of patients' rights legislation that could be adopted by the European Union, ACN worked with its original partners to draft in 2002 a charter of patients' rights (and that of their families and carers). The

charter's 14 rights echo the principles in article 35 of the 'Charter of Fundamental Rights of the European Union', but seek to make the protection afforded in the latter document an international, rather than a national, area of jurisprudence.

About Active Citizenship Network (ACN)

ACN was born in 2001 as an offspring of the 20-year-old Italian civic movement, Cittadinanzattiva. From the outset, ACN has maintained a clear agenda and method of working, and seeks to embrace as many citizens as possible into its crusade to introduce a set of legal rights to protect patients. The ACN approach draws heavily on the know-how and experience of its Italian parent.

Cittadinanzattiva has consistently tackled subject matter (whether health related or more general consumer concerns) by using a rights-based approach defined within a legal framework. The Italian consumer group also promotes active civic participation in its many campaigns. In healthcare, Cittadinanzattiva achieves this through its 90,000 members and volunteers, who staff public advice centres in hospitals, participate in the evaluation of health services, and work alongside health professionals to improve Italian health services.

The 14 patients' rights in ACN's European Charter of Patients' Rights

- | | |
|------------------------------------|--|
| 1. To preventive measures. | 8. To the observance of quality standards. |
| 2. Of access. | 9. To safety. |
| 3. To information. | 10. To innovation. |
| 4. To consent. | 11. To avoid unnecessary suffering and pain. |
| 5. To free choice. | 12. To personalised treatment. |
| 6. To privacy and confidentiality. | 13. To complain. |
| 7. To respect of patients' time. | 14. To compensation. |

ACN's 14 patients' rights fall into two categories:

(1.) Societal rights. These place an obligation on society to ensure that everybody is treated equally, without discrimination (and include patients' rights to access, information, innovation, quality, and safety).

(2.) Individual patients' rights. These are sometimes held distinct from human rights, and allow people to claim freedom of action. (Included are patients' rights to avoidance of pain, and rights to choice, compensation, complaint, consent, personalised treatment, prevention, privacy, and time.)

ACN also wishes to see citizens secure wide-ranging rights to participate in policymaking, to perform advocacy activities, and to share in healthcare activities of general interest.

For the past six years, ACN's European Charter of Patients' Rights has been a useful platform for promoting discussion. The document encourages support for patients' rights at national level and among special-interest groups.

Monitoring

During 2006 and 2007, ACN built upon its Charter by conducting ground and desk research into the extent to which the 14 patients' rights were being respected by the national healthcare services of 14 of the EU's 15 pre-expansion Member States.

The resulting report, *Patients' Rights in Europe: Civic Information on the Implementation of the European Charter of Patients' Rights*, was published in March 2007 [a summary of the report's findings can be read in "

The evidence on patients' rights', *HSCNews International*, issue 36, April 2007, pages 22-27]. The study attained several objectives. Firstly, the research managed to establish a set of 174 indicators for measuring whether countries' healthcare systems could be judged to be meeting the ACN Charter. Secondly, investigations were conducted by members of the public and by patients, in line with ACN's mantra of greater civic participation.

Once all the data were processed, they were converted into an Index of Attention to Patients' Rights (IAPR). Rights most commonly violated were found to be those that affect the person: patients' rights to have their time respected, to have freedom of choice, to informed consent, and so on. The country scoring highest

Patients' rights: progress in Italy

Teresa Petrangolini, Secretary General of Cittadinanzattiva, told the Gorizia conference about the legacy provided to ACN by its parent organisation. Cittadinanzattiva has been working on the issue of patients' rights since 1980. Italy's first national Patients' Rights Day was held in 1981. In time, some 33 patients' rights described by Cittadinanzattiva were endorsed by hospitals and health professionals (including some of the country's most reputable surgeons). Although no national laws on patients' rights have been introduced in Italy, 17 regional laws concentrate on the subject of patients rights.

By 2000, Cittadinanzattiva was regularly reporting violations of the right of citizens to high-quality healthcare. These efforts were given impetus by another offshoot of Cittadinanzattiva, the Tribunale per i diritti del malato (TDM), which literally means the Tribunal for the Sick. The TDM conducts regular civic audits on the quality of healthcare services throughout Italy.

Even with all this citizen scrutiny, Italy still only managed to rank tenth in ACN's 2007 study, *Patients' Rights in Europe: Civic Information on the Implementation of the European Charter of Patients' Rights*. Since the publication of the report, the Italian government has created a new law to promote greater continuity of care. It has also ensured that essential drugs (such as those for allergies) are reimbursed by the state, and it has refinanced a fund to compensate any patients infected as a result of a stay in hospital.

Quite rightly, Cittadinanzattiva and Tribunale per i diritti del malato (TDM) take much of the credit for these recent changes in Italian government policies.

on the Index—the Netherlands, with an IAPR of 29.5—was deemed to have Europe's best record on

patients' rights. The country scoring lowest—Portugal—only achieved a meagre 10 on the IAPR.

ACN plans to put Eastern European countries under the IAPR scrutiny towards the end of 2008.

Getting recognition nationally ...

ACN's Charter has gained recognition from many official quarters, including EU institutions. The Charter has been used as a template by the governments of Bulgaria, Estonia, Italy, and Malta. And, in 2003, the Italian Health Minister distributed the ACN Charter to all EU Health Ministries when Italy held the EU presidency.

More recently, a forthcoming Act on Patients' Rights, due to take effect in Slovenia on August 26th 2008, seems remarkably similar in content and format to the ACN Charter. At the Gorizia conference, Janez Remškar, Director-General of Slovenia's Ministry of Health, remarked about his government's belief in embracing patients in policymaking. For this reason, he said, the Act aims to provide more equitable healthcare based on trust and respect between the patient and doctor (or other healthcare professional).

Patient organisations, too, have also relied upon the

ACN Charter when setting out rights for specific types of patients. One such example is a charter that advocates rights in sexual reproduction [see box, right]. Another initiative looks at the patients' rights that are involved in the prevention and management of diabetes.

... and internationally

On March 15th and May 23rd 2007, a pair of resolutions at the European Parliament called for the "adoption of a European charter of patients' rights based on existing charters in the Member States, and on the work carried out by non-governmental organisations".

In September 2007, the European Economic and Social Committee (EESC) welcomed and acknowledged "the European Charter of Patients' Rights, promoted by Active Citizenship Network since 2002", and called upon the European Commission to establish a European Patients' Rights Day.

As mentioned earlier, Commissioner Vassiliou

The EPHA/HERA Charter of Sexual and Reproductive Rights draws on ACN's European Charter of Patients' Rights

In July 2005, the Brussels-based European Public Health Alliance (EPHA), acting in conjunction with the Moscow-based International Centre of Health Protection (HERA), issued a Charter of Sexual and Reproductive Rights. The Charter aimed to secure a positive approach to human sexuality (and include rights to freedom from guilt and from false beliefs that can impair a sexual relationship). It also articulated the right of people to be free of diseases that interfere with sexual relationships. The Charter drew heavily on ACN's European Charter of Patients' Rights.

The EPHA/HERA Charter propounded the following rights:

- The right to sexual and productive health services.
- The right to be involved in healthcare.
- The right to considerate and respectful sexual care.
- The right to freely choose.
- The right of information on sexual and reproductive health.
- The right to confidentiality and privacy.
- The right to safety.
- The right to complain and express an opinion.

regards patients' rights as part of the yet-to-be unveiled European Commission directive on cross-border healthcare.

Dr Giovanni Moro, President of the Active Citizenship Foundation (an ACN sister organisation

that specialises in promoting civic activism), insists that all of these developments in the field of patients' rights would have been unimaginable back in 2001 when ACN was formed, and when ideas of a patients' charter were first being discussed.

Next moves?

Ms Ross informed the conference that ACN has three simple missions today: the institutionalisation of April 18th as Europe's official Patients' Rights Day; more extensive monitoring of patients' rights throughout Europe; and the continuing pursuit of a European policy to ensure that every

European citizen benefits from patients' rights, not just Europeans who travel.

Given the speed and success with which ACN has operated thus far, Ms Ross probably has every chance of seeing this trio of objectives attained in due course.

What other healthcare stakeholders say



This section of the report looks at the how other healthcare stakeholders view the subject of patients' rights, and considers their alliances with ACN:

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T he judge

George Arestis, Judge at the European Court of Justice, made a presentation at a round table discussion at Active Citizenship Network's April 18th 2008 Gorizia conference, 'European Patients' Rights: a European and National Challenge'.

Thirty years ago, the Luxembourg-based European Court of Justice (ECJ) spent most of its time considering questions about product labelling and import licensing. Today, the Court's brief has extended, and it is regularly requested to assess Member State competences on subjects as diverse as criminal law, education, taxation, and even health and social security.

One of the most spectacular developments in Court jurisprudence concerns the entitlements of European citizens when they travel, live, and work in other Member States. The progressive abolition of national borders, and the increased mobility of EU citizens have raised expectations. EU citizens

* Council Directive 90/364/EEC on the right of residence, Council Directive 90/365/EEC on the right of residence for employees and self-employed persons who have ceased their occupational activity, Directive 93/365/EEC on the right of residence for students.

believe that they should now be accorded the same rights—including rights to healthcare—as people living in other Member States.

George Arestis, a judge at the ECJ, insisted that the new attitudes are generating a clash between the need to ensure an effective application of citizenship rights and the simple fact that Member States may be unable to afford to pay for these rights. An appropriate balance between the two conflicting concerns needs to be achieved.

EU legislation has already sought to specify rights (and the mechanisms for exerting them in various ways). For example, the 1990 Residence Directive* laid down strict conditions for migrants before they obtain residential rights. One such stipulation is the need for migrants to obtain comprehensive sickness insurance cover while abroad, to avoid overburdening the host country's healthcare system.

But even though legislation exists, doubts continue to persist about what health and social care mobile EU citizens are entitled to receive. Some of the travelling citizens have brought their disputes with their national and local reimbursement authorities to the ECJ. These cases have gone some way towards defining the rights of mobile patients in the EU.

The mobile EU patient

Judge Arestis said that insured migrant workers are entitled to sickness benefits in the territory of another Member State. The regulations establish that the home country must reimburse patients' expenses abroad in accordance with tariffs in the Member State where the healthcare is provided. [Article 22 of Regulation 1408/71, and matching articles 19 and 20 of the Regulation 883/2004.]

The regulations also stipulate that the home

country cannot refuse payment when the patient abroad is too sick or unwell to be able to return home for treatment.

Judge Arestis maintained that the existing system is a fair compromise between the rights of the patient and the financial concerns of the national social security systems. The patient seeking treatment abroad will receive benefits according to the laws of the host State. But the host State is able to claim compensation from the country in which the patient is insured.

The case law of the ECJ

Judge Arestis categorised five types of cases that have come before the ECJ:

- (1) Whether medical treatments are, in effect, services, and therefore comprise an economic activity that falls within EU jurisprudence.
- (2) The right of foreign EU citizens to access healthcare services in hospitals or as out-patients.

*Joined Cases 286/82 and 286/83, *Luisi and Carbone* (1984).

‡ Case C-120/95, *Nicolas Decker v Caisse de maladie des employés privés* (1998).

‡ Case C-158/96, *Raymond Kohll v Union des caisses de maladie* (1998).

- (3) The possible justifications available to the Member States in limiting access to healthcare.
- (4) The rights of EU citizens to access healthcare outside the EU.
- (5) The reaffirmation of the link between social security and free-movement principles.

Medical treatments as services

A case brought before the ECJ in 1984 (*Luisi and Carbone*) established that medical treatment is an economic activity and a service, since it is provided for through remuneration. Thus, medical treatment is covered by the provisions on free movement of services (articles 49 and 50 EC). The 1984 judgment stated that:

“The freedom to provide services includes the freedom for the recipients of services to go to another Member State in order to receive a service there, and that persons receiving medical treatment ... are to be regarded as recipients of services”.

Once medical treatment was viewed as an economic activity, then the sovereign powers of Member States could be tested against the need to ensure respect for the fundamental economic freedoms of EU citizens. This

is also why the ECJ held in the *Decker*[‡] case of 1998 that the social security sector ...

“... does not constitute an island beyond the reach of Community law”.

Mr Decker, a Luxembourg citizen, asked to be reimbursed for the purchase of spectacles delivered by a provider in another Member State. His home country refused his request. The ECJ overturned the decision.

Access to care: ambulatory services

When the ECJ established patient rights' to seek care outside their home country and have that care paid for, the extent of those rights then came under ECJ review. The ECJ was required to decide on the scale of regulatory powers that a Member State could exercise to determine when its citizens could access care abroad. This happened in the 1998 case of Mr Decker and Mr Kohll[‡], another Luxembourg citizen, who requested reimbursement for orthodontic treatment received in another Member State.

Both Mr Decker and Mr Kohll had been told by the Luxembourg statutory health insurer that they

would not be reimbursed, because neither had obtained prior authorisation for the reimbursement (on the basis of Luxembourg tariffs).

In what turned out to be seminal judgments, the ECJ ruled that the Luxembourg statutory insurance scheme

created an unjustified impediment to the free movement of goods and services within the European Union. Any national measure which has the effect of making the provision of services between Member States more difficult than the provision of services

purely within one Member State is considered a violation of the EU Treaty.

Although the cases of Decker and Kohll were specific to their personal circumstances, further ECJ case law has demonstrated that the judgments apply to

The patient advocate

Speaking at the Gorizia conference was Mike O'Donovan of the European Patients' Forum (EPF), a major NGO representing patients' interests across Europe. As part of its mission to promote high-quality, patient-centered healthcare for all, the EPF has called on the Commission to ensure that patients are provided with:

- Ω The best of healthcare as close to their home, and quickly as possible.
- Ω High-quality, timely, and accurate information in the patients' own language.
- Ω An EU Ombudsman system for patients.
- Ω A Patients' Charter as a legally-binding, apolitical instrument.

The EPF maintains that a prerequisite for the establishment of any set of patients' rights must be the involvement of patient representatives at international and national levels. The EPF has worked closely with Active Citizenship Network, and supports ACN's call for European Patients' Rights Day to be institutionalised.



In a separate presentation, Špela Polak, patient representative at Europa Donna (the European Breast Cancer Coalition), discussed the patient/public consultation processes taking place in Slovenia prior to the passage of the country's new law on patients' rights, due to take effect in August 2008. The problem faced by the Slovenian government, she said, was that patient representatives are mostly organised at a provincial level; the law, by contrast, is approved at national level. Ms Polak also spoke about government research commissioned on the subject of cross-border care in 2007. Nearly 300 patients (mostly from Ljubljana) who had received care abroad (chiefly in Austria, and some in the UK) were quizzed about their experiences. The research found that the patients had limited choices as to where to receive treatment. Information about those choices was limited, as well. Some patients with rare diseases were unable to even find an appropriate specialist.

many healthcare circumstances (beyond just teeth and spectacles).

Hospitals

In 2001, in the Smits-Peerbooms* case, the ECJ confirmed that all hospital medical care, whether in-patient or out-patient, falls within the scope of free movement of service. The Court held (paragraph 58):

“Article 50 of the Treaty states that it applies to services normally provided for remuneration, and it has been held that, for the purposes of that provision, the essential characteristic of remuneration lies in the fact that it constitutes consideration for the service in question. In the present cases, the payments made by the sickness insurance funds under the contractual, albeit set at a flat rate, are indeed the consideration for the hospital services, and unquestionably represent remuneration for the hospital which receives them, and which is engaged in an activity of an economic character”.

When defining the scope of services covered by the Netherlands health insurance, the Court went on to specify that ‘normal’

treatment constituted not just Netherlands medical science. Furthermore, the Smits-Peerbooms judgment established that prior authorisation is only required for in-patient hospital care.

The latter view was consolidated in 2003 in the Muller-Faure/Van Riet[†] case, which concerned two Netherlands patients asking their respective health funds for reimbursement. Muller-Fauré received dental treatment from a private practitioner in Germany without having obtained prior authorisation, while Van Riet received both hospital and non-hospital treatment in Belgium, after being refused authorisation by her home fund.

Justifications

The ECJ's actions against any kind of regulatory measures that impede the free movement of patients does not mean that the Court is on a mission to destroy national health systems, said Judge Arestis. The ECJ has always acknowledged that the need to ensure free movement and market integration has to be balanced with the preservation of certain public aims. This exercise in maintaining the equilibrium

of interests is one of the pillars of the European legal framework.

The Court is duty bound to ensure that national measures do not constitute a means of arbitrary discrimination, or a disguised restriction on trade between Member States. In short, the Court has to determine whether the measures adopted by any Member State are proportionate, are suitable to the aim pursued, and could not be replaced by less-restrictive measures.

Judge Arestis believed that the ECJ has shown awareness of the problems and questions currently at the centre of the debate on the reform of national healthcare systems.

Defining undue delay

In 2006, the case of Watts* further clarified yet another set of circumstances in which residents of a country can seek care abroad and have it paid for by their home

* Case C-157/99, Smits-Peerbooms (2001).

[†] Case C-385/99, Muller-Fauré (2003).

* Case-372/04, Watts v Bedford Primary Care Trust and Secretary of State for Health (2006).

country. After waiting more than a year to receive hip surgery, Yvonne Watts, a British patient, requested an E112 scheme. This scheme permits patients within Member States to seek care abroad, once they have prior authorisation. The authorising authority was a local Primary Care Trust (PCT), and it refused to authorise treatment abroad on the grounds that the delay in Ms Watts' treatment in Britain was well within the "UK government's National Health Service Plan targets", and could not, therefore, be a delay of undue length.

After a deterioration in her condition, Ms Watts traveled

to France for a hip-replacement operation. She asked the NHS to refund the costs of the operation, but it refused. Ruling on the case, the ECJ held that patients who have 'undue delay' in their treatment are entitled to be treated abroad, and for the treatment to be reimbursed. The Court defined 'undue delay' as being determined by what is clinically acceptable, not by what comprises a national norm at the time.

Treatment outside the EU

When Annette Keller[‡], a German living in Spain, paid for cancer treatment in Switzerland, the Spanish

authorities (which, until then, had agreed to reimburse her care in Germany), refused to pay for the Swiss treatment on the grounds that it was supplied in a non-EU country.

Ms Keller brought her case to the ECJ, but died before judgment. The Court found that the choices of treatment made by Ms Keller's German doctors should be respected, even if the treatment occurs outside the EU. The ECJ required the Spanish health

... Continued on page 25

[‡] Case C-143/03, Heirs of Annette Keller v Instituto Nacional de la Seguridad Social and Instituto Nacional de Gestion Sanitaria (2005).

The pharmaceutical company executive

Chris Ward, health policy consultant for the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents leading pharmaceutical and biotechnology companies from the country, was another speaker at Gorizia. Dr Ward noted that the forces which push up the costs of healthcare compel a change of view on how healthcare systems can be run. Patients should partner in healthcare decision-making. Too often, patients are denied information in the hope of curbing their demands for treatment. Dr Ward outlined four reasons why patients' rights matter:

- Ω Progressive health systems are increasingly engaging patients in decision-making.
- Ω Engaging patients in decisions about their own care is the most effective weapon against market-access restrictions.
- Ω Patient-centered care is shaping healthcare and primary care reform around the world.
- Ω Patient engagement matters to health plan sponsors who care about outcomes.

The hospital administrator

Pascal Garel, Chief Executive of the European Hospital and Healthcare Federation (HOPE), spoke about the Federation's work in the area of patients' rights. As far back as 1979, HOPE had adopted the European Charter of Hospital Patients' Rights. Mr Garel said that the Charter has had some influence in at least nine European countries, mainly in litigation/compensation, and in the acceptance of a 'no-blame' culture.

Nonetheless, Mr Garel considered that much more could be done. Referring to statistical charts, he explained that continued disparities in the health of individuals across Europe are driven, in part, by the pressures on national financial resources. He observed that Europeans are facing differences in life expectancy according to where they live, and also in the quality of their own personal health. Education, he felt, would iron out these gaps. "Better-educated people can live about ten years longer than the less well educated," he said.



Laure Albertini is Director of the Department of Patients' Rights and Associations at the Assistance Publique—Hôpitaux de Paris (AP-HP), the public hospital system of Paris. AP-HP is responsible for 38 hospitals, 23,000 beds, and 90,000 healthcare professionals. The system manages 3.6 million consultations each year and one emergency admission every second.

Ms Albertini described how patients' rights were afforded legal status in France in 2002, following a build up of patient and public involvement in health issues. Up until that point, the only rights accorded to French patients were those given to them by professional codes. Patients had no direct access to medical records, and patients could only obtain medical compensation if they could prove fault.

The 2002 development was of major symbolic significance, said Ms Albertini. It empowered patients by enabling them to participate in medical decision-making processes, instead of merely being passive accessories in the paternalistic doctor-patient relationship which prevailed before. Secondly, the rights of patients in cases of medical error were clarified. The 2002 patients' rights law took years to develop, but, said Ms Albertini, is ambitious in its scope as a result. The law includes:

Ω A patients' right to be assisted by a person of the patient's own choice.

Ω The right for minors to have direct access to medical care without their parent's consent (under certain conditions).

Ω The introduction of a new compensation system, and an alternative to judicial courts (restriction to access is based on the gravity of the injury).

A commission has been created in hospitals to improve patients' rights. At national level, patient representatives have been introduced to play a role in the strategic organisation of the public health system. But, despite progress, Ms Albertini was certain that the process of enforcing patients' rights should be tracked at European level. "The need to change the mentality of those who oppose patients' rights", she insisted, "is great".

A summary of patients' rights, as determined by the ECJ

1. Medical treatment (including that delivered within and outside hospitals) is an economic activity and service. As such, medical treatment is subject to EU laws governing free movement of goods. Patients living in the EU are afforded the same rights as citizens utilising any other types of services located within an EU country.
2. EU patients seeking care (and reimbursement) outside hospitals, or as out-patients within hospitals in another Member State do not require prior authorisation from their home country to do so.
3. EU patients seeking care (and reimbursement) as in-patients within hospitals in another Member State do, however, require prior authorisation from their home country.
4. EU patients are entitled to receive (and be reimbursed) for health services/ treatment in another Member State even if that service/treatment is not available in their home country.
5. EU patients are entitled to receive (and be reimbursed) for health services/ treatment in another Member State if their domestic healthcare system has imposed delays that clinically comprise the patient. The definition of undue delay is therefore determined by what is clinically acceptable, not what is the national norm. In such a case, prior authorisation is not required.
6. EU patients are entitled to receive (and be reimbursed) for health services/ treatment in a non-Member State, if those delivering care within the EU make that recommendation.

insurance to reimburse her family.

Social security and free movement principles

Towards the end of his presentation at Gorizia, Judge Arestis discussed a case from early 2008—that of the Government of the

French Community and the Walloon Government v the Flemish Government*.

In the case, the ECJ was asked whether a care insurance scheme for disabled people adopted by the northern Flemish region was applicable to people who worked in the area but lived

in another part of Belgium. The Court found that the limited access was a contravention of the principles of the free movement law, and stated:

“Migrant workers, pursuing or contemplating the pursuit of employment or self-employment in one of those two regions, might be dissuaded from making use of their freedom of movement, and from leaving their Member State of origin, to stay in Belgium, by reason of the fact that moving to certain parts of Belgium would cause them to lose eligibility for the benefits which they might otherwise have claimed.”

Final Observations

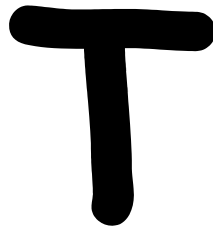
Judge Arestis admitted that these cases raise difficult questions, especially in circumstances where funds for healthcare are limited. He also agreed that the ECJ has been criticised for treating healthcare as a service industry, rather than as a social necessity.

Nonetheless, even when working to promote the principle of universal and equal access to healthcare, the Court has not forgotten

* Case C-212/06, Government of the French Community and Walloon Government v Flemish Government case (2008).

the important consideration of ensuring the financial stability of national healthcare systems. Hence the ECJ has allowed the continuation of the prior-authorisation system for in-patient hospital treatment abroad. Judge Arestis cautioned, though, that when a patient's condition is urgent, a prior-authorisation procedure cannot be tolerated, even for hospital treatment.

Concluding, Judge Arestis said that in a period when patients behave as well-informed consumers, national social security and healthcare systems should not neglect cross-border aspects. But he acknowledged that the role of Court is limited, and suggested that it might be time for other European institutions to step in with a political solution.



he primary-care health professional

Pim de Graaf, who acts as adviser to the World Health Organization on primary healthcare matters, discussed the issue of patients' rights in his specialty. Dr de Graaf is also on the board of the European Forum for Primary Care (EFHC), which seeks to promote the role of primary care providers in healthcare systems.

In the view of Dr de Graaf, all primary healthcare providers (be they general practitioners, nurses, medical assistants, or physiotherapists) should aspire to four goals:

Ω Accessibility: providing accessible care without barriers of distance, financial, cultural, or other.

Ω Comprehensiveness: providing a wide range of services, not just one or a few (to include curative care, home care, long-term care, prevention, and the promotion of preventive practices).

Ω Co-ordination: ensuring that different services are provided in coordination; helping the patient to navigate through the healthcare system.

Ω Continuity: ensuring that information is generated, and kept over time, on the patient's health history (also means personal continuity).

Yet these four elements, he insisted, are not always fully developed in every EU country. This may be due to the mix of professionals available, the different modes of funding, and the various organisational set-ups present—in particular, whether health providers are salaried employees, or private entrepreneurs.

The best performers tend to be organised as teams, with regular patients. Where GPs are charged with acting as gate keepers, they direct patients to those who best provide care (a system which is finally being introduced into France and Germany, despite public protest).

A degree of overlap occurs between the ambitions of the primary healthcare provider and the patient who wishes to be afforded specific rights.

Both groups agree that access, free choice of treatment (though not unconditionally), the observance of quality standards, personalised treatment, and prevention should be the cornerstones of any healthcare system.

In developing any patients' rights' agenda, contended Dr de Graaf, attention needs to be paid to the fact that patients are idiosyncratic. They may be young or old, in work or out of work, overweight or underweight, have a disability, or even multiple conditions. Whose perspective among these variations should be paramount, if any? To answer such a question, more information is needed about what patients value and find important in their primary healthcare provider.

Conferences on primary healthcare: developing a tool to examine the quality of care

Examining the quality of primary healthcare providers from the perspective of patients was the main topic of the international

'Ljubljana Patient 2008' conference, held in Ljubljana, Slovenia, on March 28th-29th 2008. [<http://www.ljubljanapatient2008.si/preconference.html>]. Active Citizenship Network was one of the presenters.

The conference aimed to develop a tool for assessing primary care through the eyes of doctors, policymakers, and also patients. The tool is due to be launched later in the year, and made available to national ministries of health and to various organisations (including patient groups) across Europe.

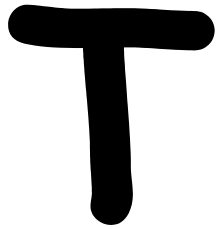
Conferences on primary healthcare: developing the optimum primary healthcare system

According to the World Health Organisation [WHO publication EUR/07/5073818 January 14, 2008], people's participation in decisions that affect their health is rights-based, and does not therefore have to be justified through evidence. On the other hand, more research needs to be done into the

impact that user empowerment has on the performance of healthcare systems.

On June 25th-27th 2008, a WHO-European Ministerial conference, 'Health Systems: Health and Wealth', takes place in Tallinn, Estonia [<http://www.euro.who.int/healthsystems2008>]. The conference is scheduled to be attended by ministers of health from the 53 Member States that comprise the WHO's European Region. Up to 500 participants (including patient organisations) are likely to be at the event.

Conference discussions will centre on how primary healthcare can become a foundation of good healthcare systems. The intention is to develop a Health Charter that can provide guidance and a strategic framework for strengthening healthcare systems throughout the WHO's European Region.



he community pharmacist

Lilijana Grosek, representative of the Pharmaceutical Group of the European Union (PGEU), talked of patients' rights from the perspective of community pharmacists across Europe. PGEU pharmacists celebrated European Patients' Rights Day as a way of expressing their commitment to the dissemination of the European Patients' Rights Charter.

Ms Grosek began her presentation at Gorizia by pointing out that patients' rights mean little if the patients themselves, or their carers, family, or friends, do not know about, or understand, such rights. People who are not fully informed cannot evaluate whether the best-possible care is being provided to them, she stated.

Accessible information

Ms Grosek said that information about medicinal products should not merely be presented in formats accessible only to people who can comfortably use information technology. Nor should it always be couched in technical clinical and pharmaceutical terminology. Dissemination should include members of society—often those most in need of appropriate information—who prefer traditional forms of information provision (such as leaflets or posters).

Community pharmacists, explained Ms Grosek, have an ethical (and, in some countries, even a legal) obligation to supply information on all sorts of healthcare matters.

Health outcomes

According to Ms Grosek, the dissemination of information should be consistent with the improvement of health outcomes in society overall, and not simply be for the benefit of individuals. Key to this idea are concepts such as sustainability, solidarity,

universality of access, and public confidence in healthcare systems.

The role of the pharmacist

Pharmacists contribute to personalised information on healthy lifestyles, as well as to national, regional or local information campaigns aimed at preventing diseases and lowering disease risk factors (examples include healthy diets; non-smoking; physical activity; and sun protection to avoid skin cancer).

A change for the worse?

Traditionally, community pharmacists have been small independents located at the centre of neighbourhoods, where they can easily be reached by the local population—whether in rural areas, suburbs, or deprived inner city locations. Ms Grosek thinks that the traditional model of the community pharmacy is now under threat within some Member States. The growing trend for liberalisation of the industry has forced out smaller independents, leaving only the branches of large pharmacy chains. In her view, such a development contravenes the patient's right to free choice, and critically limits the public's ability to choose between pharmacies.

In addition, by ensuring the appropriate use of medicines, pharmacists help avoid unnecessary complications that may result from the progression of the disease that is being treated, or from medication itself. This service helps patients exercise their right to personalised treatment, and is also intrinsically linked with the right to avoid unnecessary suffering and pain, and with the right to safety.

Ms Grosek applauded some Member States' moves to engage community pharmacists in the system for reporting suspected adverse reactions to medicines and side effects. Patients are often likely to ask their pharmacist about problems encountered with prescription medicines, noted Ms Grosek. Community pharmacies also ensure

traceability, provide a security net for medicines, help prevent counterfeiting (and detect it, if it occurs), and participate in the recall of medicines, if necessary.

Furthermore, systems of collection and disposal of unused and out-of-date medicines through pharmacies are already functioning in most EU Member States, although the organisation of these systems is far from uniform.

Ms Grosek ended her talk by saying:

“Of course, patients' rights are about patients. This is why we see the overriding importance of involving patients in initiatives such as European Patients' Rights day, which certainly puts the focus on patients”.



End of report

*“There is an infinite amount of suffering in the world,
but only a finite amount of money to spend on its mitigation.
It was always so, and will always be so.”*

—Charles Foster, ‘Healthcare funding in the real world’, *New Law Journal*
<http://www.ethics-network.org.uk/commentaries/health-care-funding-in-the-real-world>

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