SPECIAL REPORT
ACCESS TO HEALTHCARE

Healthcare in the time of crisis


REUTERS

The financial crisis has put great strains on healthcare systems across the EU, writes Dave Keating

Europe is now in its fifth year of a grinding economic crisis that has affected the daily lives of Europeans in many ways. One of the most profound effects has been on the provision of healthcare.

In Greece, austerity imposed by the government at the request of international lenders, including the European Central Bank and the EU, has forced cuts to the spending of hospitals and other healthcare providers. Doctors and other medical professionals have been laid off. What was already a poorly functioning health service is plagued with long waiting times and poor care.

It is not only in Greece that the economic crisis has affected citizens' access to healthcare. In Spain and Bulgaria, the healthcare systems have creaked badly. As the need for care increases, the financial resources to pay – whether on the part of the state or the individual – have decreased. Citizens are asked to contribute more for their care, which puts care out of the reach of some. The principle implied in EU law that treatment should be accessible to every patient who needs it is under strain (see page 14).

The crisis has had other significant effects on healthcare in the EU. It has given the EU institutions an unprecedented level of control over national healthcare decisions.

Officially, the EU still has only a limited competence to make policy in the field of health – it is for member states to make decisions about their own healthcare systems. But the introduction of greater surveillance of national budgets – through the European Semester – has involved the European Commission in national healthcare decisions. Under the European Semester, the Commission makes recommendations about healthcare, social security and pensions.

Although the semester programme was started in 2010, as the eurozone felt the need to ratchet up powers to enforce more disciplined economic governance, examination of national healthcare spending did not start until last year. Now, the Commission has a degree of scrutiny over national healthcare decisions, and has been tasked with making sure healthcare funding is not only being spent wisely, but also maintains a fair degree of access.

Campaigners for vulnerable groups such as the poor, the disabled and those with rare diseases increasingly see an opportunity, even a need, to turn to the Commission as the guarantor of patients' rights.

The semester is not, however, the principal way that the EU looks to improve and guarantee access to healthcare. More directly, the EU has passed legislation that looks to set some common standards about the provision of healthcare.

A law on cross-border healthcare is supposed to codify patients' rights to get access to healthcare in countries other than their own. Patients can go to another EU member state if the operation or treatment they need is not available in their own country in a timely manner. The legislation also imposes obligations on national healthcare systems to be transparent about pricing, which will force some member states for the first time to put prices on their medical procedures. The EU hopes this will reduce wasteful spending and improve access to healthcare for patients. EU measures to encourage e-health are also seeking to increase information and access (see page 16). The technological possibilities are growing all the time, though so also are the possibilities of a digital divide in which the technologically savvy patient has greater access to more, better and cheaper care than the technologically illiterate.

Increasingly the EU is also getting involved in the quality of care. The health scare about faulty breast implants from PIP fed fears about the safety of medical technology and procedures. Calls for changes in approval processes are growing, even while the possibilities for patients to buy procedures or medicines outside the traditional channels proliferate. Last week the European Parliament approved EU-wide rules for conducting clinical trials on medicines and agreed a first-reading position on EU approval of medical devices.

The landscape of healthcare is changing rapidly on many fronts. The challenge for the EU is to ensure that access to healthcare keeps pace with technological changes to care and its delivery.

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Too poor to be treated?

There are huge gaps between member states when it comes to healthcare provision, writes Cynthia Kroet

In the European Union, one of the most important determinants of an indvidual's access to healthcare is what country he or she lives in. The EU's treaty sets out that: "Union action shall respect the responsibilities of the member states for the definition of their health policy and for the organisation and delivery of health services and medical care."

The treaty does give the EU a role in public health. It requires that: "A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."

And it dictates that: "Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health."

But while the European Union's Charter of Fundamental Rights states that "everyone has the right of access to preventive healthcare and the right to benefit from medical treatment under the conditions established by national laws and practices", what matters most are those national conditions: a member state's definition of its health policy and the organisation and delivery of services and care.

Although European member states have, by global standards, well-developed healthcare systems, equality of access for all is still far from reality. In practice there are considerable variations in care between member states and within each member state.

The World Health Organization Europe (WHO) is mapping out groups that are excluded from, or lack sufficient access to, medical treatment. This exclusion is usually determined by social and economic circumstances such as income and living conditions.

National policies on public funding for healthcare, or reimbursement or the funding of specific therapies or technologies also determine access to care. Nicola Bedlington, director at European Patients Forum (EPF) – a Europe-wide federation of patients' groups, which seeks to represent patients' interests across member states – says: "There is a huge gap between member states and it is even deepening because of the economic crisis."

Across the EU, financing demands for healthcare are rising faster than economic growth. The net effect is that healthcare becomes less accessible. A WHO Europe survey shows that in the EU about 30% of citizens say it is more difficult to bear the costs of general healthcare than before the crisis.

The EU is striving to reduce inequalities and inconsistencies. Its health programme for the spending period 2014-20 has as one of its main aims reducing discrimination in healthcare.

Tonio Borg, the European commissioner for health, has promised that this programme should be able to "improve people's access to medical expertise and information for specific conditions, and improve healthcare quality and patient safety".

One of the more specific elements in the new programme is improving health literacy, by which the EU means the ability to get information understood by appropriate audiences. "In the end, access is all about information and education. If patients are not aware of their rights and possibilities it could have a serious impact on their health," says Bedlington.

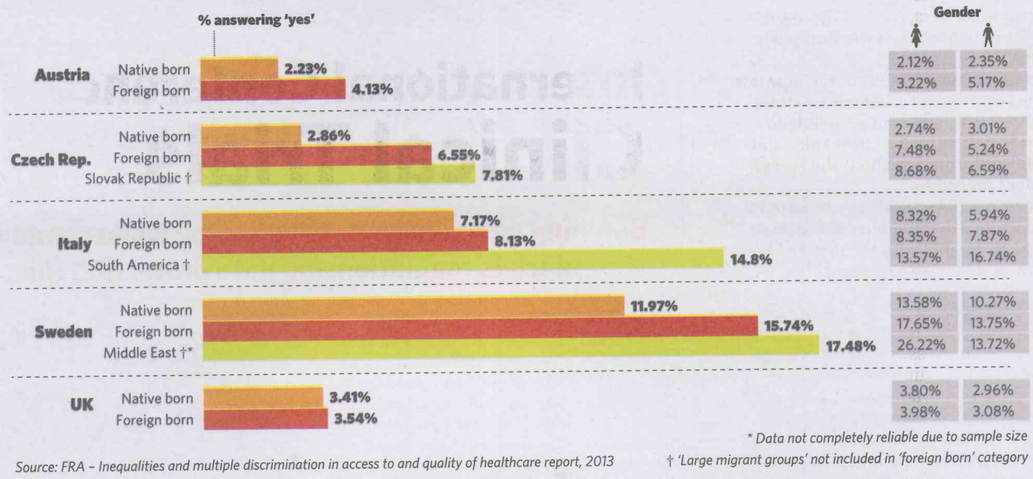
She says there are sub-categories of patients that might find it increasingly difficult to get access to medical treatment. "Healthcare professionals could think it is not worthwhile any more to invest in old patients, for example." She cites as an example attitudes to depression, which has been seen as a condition of old age.

Patients that experience rare diseases may also encounter difficulties in getting access to healthcare services. An estimated 27 to 36 million Europeans suffer from such a disease, so the EU is supporting research to improve diagnoses and treatments.

According to Serge Bernasconi, chief executive officer at Eucomed – an organisation that represents the medical technology industry in Europe – the industry is trying to offer solutions: "We develop new technologies – such as medical devices and in vitro diagnostics – that are more value-based and that meet the needs of patients."

But Bernasconi is not optimistic about the impact of the economic and financial crisis on the health sector: "When it comes to healthcare sustainability, we don't think the old days of virtually no restrictions on healthcare budgets will ever come back."

Unmet need for medical examination or treatment



Source: FRA – Inequalities and multiple discrimination in access to and quality of healthcare report, 2013

** Data not completely reliable due to sample size*

† 'Large migrant groups' not included in 'foreign born' category

Where science leads, legislation tries to follow

EU moves towards a single market for medicines still face national obstacles, writes Peter O'Donnell

Medical technology has transformed healthcare over the last century – but rising expenditure on drugs is disquieting ministries in member states where funding decisions are made, while consumer concerns, amplified by a rising tide of scepticism over technology, are leading to ever-stricter demands for safety. This is the shifting background against which current European Union debates on access to treatment are increasingly taking place.

Successive rounds of EU legislation over the past 60 years have imposed an accumulation of requirements on drugs, devices and diagnostics – and continue to do so, in response to advances in science. The EU exerts almost total control, with authorisation decisions issued only after satisfactory completion of rigorous sequences of tests and trials. In contrast to decisions on whether a drug can safely be put on the European market, decisions as to how much it will cost and who should pay remain entirely a matter of national competence.

But both of these approaches are now under fundamental review.

The European Medicines Agency, at the heart of the authorisation process, has admitted that the safety system it governs may have become too rigid, and be impeding access to potentially valuable medicines. In March it formally launched a pilot programme to explore a more flexible authorisation procedure, in which the blunt "Yes/No" decision-making after perhaps ten years of testing and trials might be replaced by an earlier, gradual, and closely monitored exposure to progressively wider patient populations. Hans-Georg Eichler, the agency's senior medical officer, who is one of the leading architects of this so-called 'adaptive licensing', describes it as an attempt to "maximise the positive impact of new drugs on public health by balancing timely access for patients with the need to provide adequate evolving information on benefits and harms".

On pricing and reimbursement too, radical new thinking is evident, prompted by the inconsistency between a single marketing authorisation valid for as many as 30 countries, and the 30 different decisions on whether the medicine should be paid for, based on 30 different methodologies.

The current process fully respects national sovereignty, but in so doing it is – as many national authorities now recognise – wasteful of time and resources, and can lead to inequalities of access between member states. So pricing bodies in the member states – such as health ministries or insurance organisations – are now working more closely together to see if they can agree at least on the criteria and methodologies they should employ, even if they retain the right to make their own decisions at the end of the process.

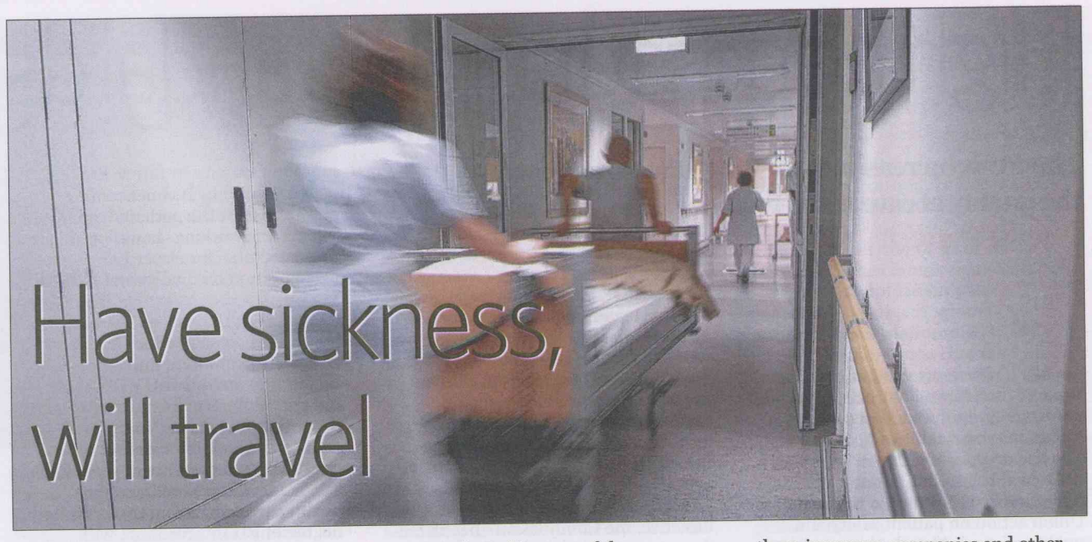
The EU is promoting these moves in the interests of making progress towards more of a single market in medicines. And there is cautious backing from the drugs industry, which sees potential efficiencies in avoiding duplicative processes. But neither of these initiatives is likely to move fast. Every revelation about a new side-effect strengthens popular calls for tighter controls on safety and re-ignites anxieties about any suggestion of simplifying authorisation processes. The complexities of drug pricing and reimbursement continue to defeat even timid EU attempts to legislate on the matter. That was amply demonstrated by the loss without trace of the European Commission's 2012 draft directive on drug pricing methods, in the face of hostility from the member states.

Within the drug industry, which is the source of nearly all candidate drugs, the concern is often expressed that tinkering with the details of the rules may not be enough. Drug firms say what they most need are assurances that Europe can offer a market to innovations that will incentivise further research.

Behind the scenes, even more radical approaches are now being considered and discussed that could lead to industry, regulators and payers working more closely together in a significantly different relationship, so that they share the risks and the benefits of creating new medicines and bringing them to the patient.

After decades of a confrontational approach to drug innovation, the next 12 months could see the start of some more co-operative thinking and action.

Have sickness, will travel



Travelling across borders to receive treatment could become easier, writes Cynthia Kroet

It is not yet common for patients to travel across national borders for routine surgery, such as a hip-replacement or a hernia operation, but it could become more frequent.

Cases in the European courts and the EU's recent law on cross-border healthcare have established that patients do have rights, albeit circumscribed, to seek treatment abroad. In the case of hip-replacements or hernia operations, it is not that hospitals in their home country could not offer such operations, but the waiting times might be shorter abroad. For other conditions, some member states might offer more specialised care. The cross-border healthcare directive adopted in 2011 makes it easier for patients to get treatment abroad and, if prior consent has been obtained, have the home country's healthcare system pay for the treatment.

In theory, it is an important step forward in expanding access to healthcare. Tonio Borg, the European commissioner for health, described 25 October 2013, which was the deadline for member states to put the EU law into national laws, as an "important day for patients across the European Union".

An important element of the new law is the requirement for member states to set up national contact points to provide patients with "clear rules and reliable information about the [cross-border] procedure".

However, *European Voice* reported last October that member states were failing to comply with the new EU law and most had missed the deadline to put the directive into national legislation. Only a few had set up the websites that are required to provide the necessary cross-border transparency. Spain, which opposed the legislation, is far behind on transposing – and looks like taking several years to implement it.

By now, 25 member states have sent the European Commission details about the current state of play. "Before the summer we will review this information and decide if we continue with infringement procedures against countries that have failed to implement the law," a spokesperson for the Commission said.

When the transfer into national law is complete across 28 countries, it is estimated that about 1% of patients will be availing themselves of cross-border healthcare. The Commission says a vast majority of patients would still prefer to receive treatment in their own country. It also warns that patients must satisfy certain conditions before they get care abroad. "We have to manage expectations," Borg said. "If we tell people that anyone can go anywhere and get healthcare, we would be doing a disservice to the directive."

The new law's impact on overall access to healthcare will be limited, says Serge Bernasconi at Eucomed, an organisation representing the medical device industry. "National and regional authorities continue to decide what kind of healthcare is being offered in their member state or region. The access to healthcare only increases when there are capacity problems and long waiting-lists [in the home country] and a willingness of health authorities to support patients in receiving healthcare in other member states."

Even once the laws are all in place, there is still much to do to develop effective information services that will encourage patient mobility. A recent survey has shown that 60% of organisations representing patients in member states know about cross-border healthcare possibilities.

"One of the problems is the lack of data from different member states," says Nicola Bedlington of the European Patients' Forum. "In many cases, patients do not know about the possibilities to receive cross-border healthcare and neither do insurance companies."

A lot will depend on the attitudes of those insurance companies and other organisations that foot the bill for patient care. If they embrace the possibilities of EU law, convinced that better and cheaper treatment is available abroad, they could give a boost to the take-up of cross-border care.

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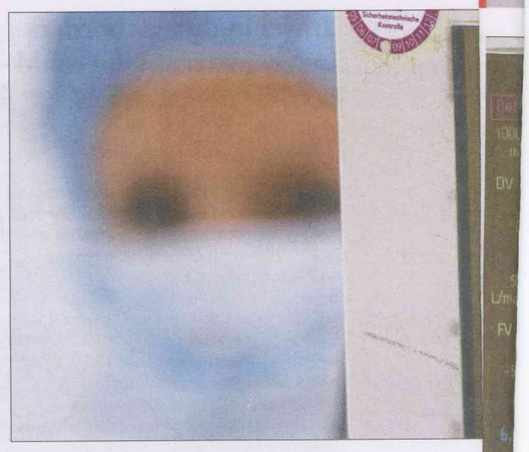
High hopes for high standards

The EU is increasingly looking at ways to improve the quality of care in the member states, writes Peter O'Donnell



Faulty breast implants in France, suspicious deaths in UK hospitals, and shortages of anti-cancer drugs in Germany and Italy are just some of the failings that have given new urgency to decade-long European discussions on quality of healthcare. The European Commission says that "2014 will be an important year for reflection on the future of European Union action on patient safety and quality of care". Already this year, the reflections have provoked a lively discussion among member states on the idea of introducing EU standards for healthcare.

In deference to the EU's limited competence for health, the approach to quality has until recently left most of the responsibility at national level. Conclusions agreed in the Council of Ministers back in 2006 typifed this approach: "Good quality care... is achieved in particular through the obligation to continuous training of healthcare staff based on clearly defined national standards". But the adoption in 2011 of a directive giving patients new rights to routine healthcare in other member states (see page 15) has triggered new thinking, and an EU-funded programme among national health authorities is now halfway through a three-year plan to improve patient safety and quality of care.

Inspired by the patients' rights directive, the Commission's health department has gone one step further. It is now planning a feasibility study "to define conditions under which standards for health services could be developed, including in relation with clinical standards". France, backed by other member states, has immediately objected that quality remains a national matter. But the debate will intensify over coming months. It will be fed notably by the Commission's soon-to-be-published results from a consultation that asked whether quality of healthcare should be given more importance in future EU activities, and by its forthcoming report on how the patients' rights directive is working, as well as a projected plan for closer EU collaboration on quality and patient safety.

If discussions over maintaining quality are presenting headaches, the questions over maintaining access to quality care are proving even more inflammatory. Healthcare costs continue to rise, while budgets continue to tighten. Member states have admitted over recent years that the financial crisis was harming healthcare – and this provoked a new degree of EU intervention, with unprecedented guidance on national budgeting. As the Commission's consultation document on quality care puts it: "This is why – within the European Semester exercise – the Commission encourages member states to prioritise access to high quality healthcare while reforming their health systems." However, the new pressures of austerity are just an additional strain alongside the well-recognised healthcare challenges of an ageing society, inequalities of access, and growing demands for expensive technology. Tonio Borg, the European commissioner for health, speaking earlier this year about health inequalities, observed: "The health gap – for example between rich and poor and between certain social groups – has not narrowed. In some instances the gap has actually widened."

With little prospect of healthcare budgets increasing to keep pace, many current suggestions as to how wider access can be achieved without a loss of quality tend towards the aspirational or inspirational. Katrin Fjeldsted, president of the standing committee of European doctors, insists that: "Access to high quality healthcare is a fundamental right of every patient, and

The (un)informed patient

Having the correct information about treatment can have life-or-death consequences, but patients are often left in the dark, writes Cynthia Kroet

Healthcare professionals generally think that they have clearly explained possible treatments to patients and given sufficient information for an informed choice. However, research studies repeatedly show that the perception of patients is different. Although the successful treatment of most conditions depends on the understanding and co-operation of the patient, patients frequently complain of a lack of information. Improving access to healthcare often involves improving patients' access to information.

In June 2013, the EU updated legislation covering the information that must be conveyed to patients in the packaging of medicines. The theory is that patients are told the possible risks and side-effects of the drugs that they take. In practice, the information is likely to be so complicated as to be ignored by patients.

The transmission of information from doctor (or drug company) to patient is very important – and very difficult. It is not just that patients frequently forget what they have been told, and neglect to follow instructions. The PIP breast implant scandal affected some 400,000 women in 65 countries. It turned out that breast implants by the French company Poly Implant Prothese (PIP) had a higher rupture rate than implants from other brands. In such cases, getting hold of information – and knowing what importance to attach to it – have serious health consequences. The safety of patients can depend on getting access to information and acting on it.

The European Commission has proposed greater supervision of the organisations in member states that are responsible for the inspection of medical devices that are implanted in the human body. Last week (2 April), the European Parliament approved these new rules, siding with stronger supervision and improved traceability.

But the legislation is no guarantee that patients will be well informed about the procedures and possible risks. The legislation might strengthen the hands of regulators, but it will not necessarily make for a better informed patient.

Advocates of eHealth services are convinced that digital technology can provide ways to improve the flow of information between health professionals and patients. Patients will be able to convey information about their condition to clinicians and practitioners. In turn, clinicians can convey information and explanations of treatments. Developments in electronic health records and healthcare information systems promise to put the patient at the centre of the information network. eHealth is becoming more widely used in EU member states, with Denmark, Estonia, Sweden and Finland leading the way.

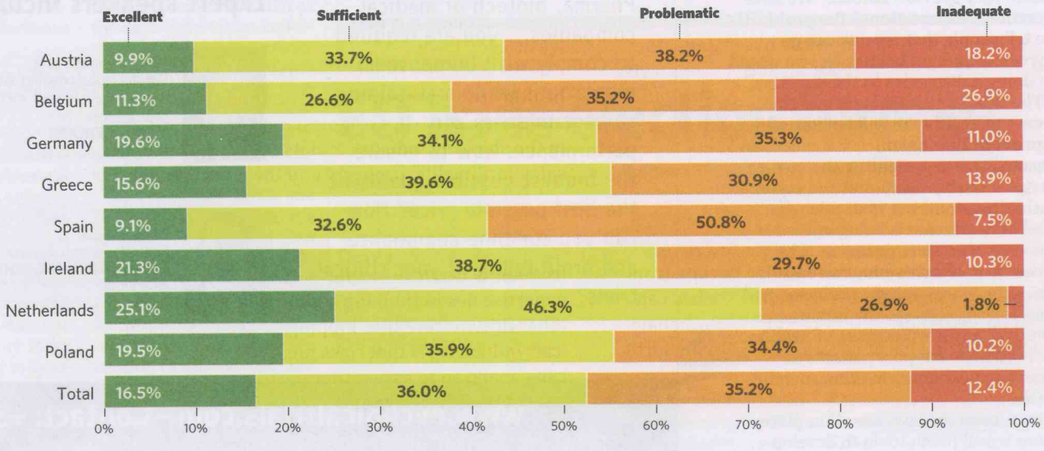
Unsurprisingly, Neelie Kroes, the European commissioner for the digital agenda, is championing the potential of digital technology to improve healthcare. She has said: "By making the most use of digital tech, we can reduce costs, put the patient back in control, make healthcare more efficient and help European citizens to take an active part in society for longer."

Hospitals and healthcare services have been using electronic services for traditional medical recording and reporting. But most advocates of eHealth see that it will involve a switch, so that patients have access to their own medical data, which is increasingly the case in some countries, notably the Netherlands and Denmark. At the moment, only 9% of hospitals in Europe allow patients to have online access to their medical records.

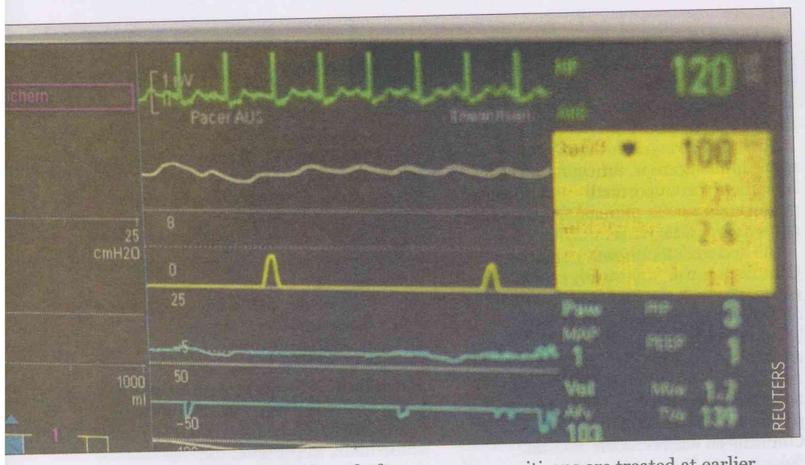
However, at the same time, patients have much more information available on the internet about medical conditions and treatments – unmediated by consultations with medical professionals. There is currently a mismatch between the information available to patients about health and disease in general and their own personal conditions. Additionally, healthcare organisations are often unwilling to make freely available on the internet information about quality and cost of care.

Serge Bernasconi, chief executive officer at the devices industry association, Eucomed, says: "Currently, there is little information available for patients about which therapies and products are available in which

European general health literacy levels



Source: The European Health Literacy Project 2009-2012



medical need should be the only factor which determines the provision of healthcare." Nicola Bedlington, director of the European Patients' Forum, says: "It is unacceptable from the patients' perspective to choose between quality and access." Peggy Maguire, president of the European Public Health Alliance, says: "Quality care can be maintained while improving access. If appropriate frameworks are in place to uphold standards of care, then healthcare professionals will know what is expected of them." Paul De Raeve, secretary-general of the European Federation of Nurses, claims that far from endangering quality of services, wider access "increases it as more citizens are treated at earlier stages", improving prevention. Roberto Frontini of the European Association of Hospital Pharmacists suggests the answers lie "in innovative mindsets, for instance identifying areas of potential waste that can release resources to be used elsewhere, such as in achieving better outcomes from medicines expenditure".

The healthcare lobby's determination to increase access and improve quality is understandable. But whether this aspiration materialises will depend heavily on the policies adopted by finance ministers – and on how far the EU can find ways to achieve the two objectives simultaneously.

country, what their value is and how they are best used in the entire care pathway. This information is available as technology assessment reports, but they are often not easy to understand for patients."

In this field, as in so many other realms of healthcare, there is an obvious risk of a divide opening up: the informed, connected patients will be given ever greater access to information that can improve their healthcare; the uninformed, excluded patients are in danger of being left behind. For the EU, this is a disturbing prospect.

Equal care for all?

Much of the national and European policy that this special report examines has relied on a central assumption that greater access to healthcare is both desirable and possible, but is it?

Because of the economic crisis, national governments are acutely aware of how financial constraints can separate what is desirable from what is achievable. Some healthcare systems in Europe already labour under severe constraints: greater access and greater demands on those systems could expose their unsustainability.

Although health ministers do not like admitting as much, universal access to healthcare remains an aspiration rather than a reality. Would healthcare systems be able to cope if everyone really did have the same level of access? Setting goals of increased access and increased use of health systems while cutting spending on health and social systems is, on the face of it, contradictory. At the very least, engineering a revolution that extracts more output from less input usually involves some initial investment.

In December, the Council of Ministers issued conclusions looking at the sustainability of European healthcare systems. It placed great emphasis on cost effectiveness, but stressed that "over the course of the first three European Semesters, the role of health issues has been consistently reinforced...with the twin aim of ensuring equal and universal access to high quality healthcare as well as funding based on solidarity principle and a more efficient use of public resources".

Finding the right balance between increasing access to healthcare and controlling spending on healthcare will be the unenviable task not only of national governments, but of the European Commission in assessing budgets within the European Semester.

Dave Keating