

THE NEW EU HEALTH POLICY AND THE NHS SYSTEMS

Scott L. Greer



The Nuffield Trust
FOR RESEARCH AND POLICY
STUDIES IN HEALTH SERVICES

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The Constitution Unit
School of Public Policy
University College London

Foreword by John Wyn Owen CB



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59 New Cavendish Street
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Telephone: 020 7631 8450
Facsimile: 020 7631 8451

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FOREWORD

On 15th July at a conference on the Future of Health in Europe, David Byrne, EU Commissioner for Health and Consumer Protection, said:

*“The only way to achieve good health for all is to put health at the centre of EU policy making, positioning good health as a key driver of economic growth, fostering long-term investment in health, bridging the health gap and tackling inequalities to ensure that good health is possible for each and every citizen in every city, region and country across the EU, working harder to ensure that all EU policies are good for health and building capacity to protect citizens from health threats, from pandemics to bioterrorism to HIV/AIDS.”**

This briefing paper sets out mechanisms which bring the EU into health services policy and then discusses the emerging opportunities and challenges for the family of health services in the United Kingdom. This research, supported by the Nuffield Trust, builds on the original grant to the University College London Constitution Unit on the impact of devolution on the NHS and is part of the Trust’s programme on the Changing Role of the State and the Machinery of Government for Health Policy, which focuses on globalisation, regionalisation and devolution.

The intention of both the Trust’s programme and this particular publication is to ensure that policy makers across the health services of the UK develop an appreciation of the European dimension and develop their skills on EU politics and administration before the rules of the game are set by others.

John Wyn Owen CB
Secretary
Nuffield Trust
January 2005

* European Policy Centre conference on 15th July 2004, *Future of Health in Europe*. D.Byrne Speech/04/367.

THE NEW EU HEALTH POLICY AND THE NHS SYSTEMS¹

“We’re sitting on the tracks, watching the EU coming at us and thinking about doing something”
- Scottish Executive Health Department official, Edinburgh, April 2002

“There’s this buzz around health policy in Brussels... everybody thinking it’s the big new policy area – but I’m not sure what the policies are actually about”
- European affairs lobbyist, London, March 2004

There is a lot to occupy anybody working in or concerned about the health systems of the United Kingdom. There are challenges of organisation and management: Payment by Results, patient choice, and diversity in England, the Review of Public Administration in Northern Ireland, waiting lists in Wales, hospital rationalisations in Scotland, to name just a few. There are powerful political imperatives handed down from above. There are high-level political pressures on ministers from all around, as diverse as controversies over injections and arguments over the usefulness of “modern matrons” in hospitals. There are all the problems of complexity, management, and professionalism that always bedevil health service administration. And there are major long-term issues – obesity, the return of communicable disease, ageing populations.

And then there is Europe. For a long time the EU has been on the back burner, largely confined to innocuous or benign public health powers and small-scale spending programmes on medical research or public health promotion. But that is rapidly changing.

Of all the threats and opportunities facing the NHS systems in the near future, the development of European Union health policy should be the most important. This might seem like an odd claim, given the many issues facing health services. But there is powerful

1. I would like to thank Charlie Jeffery, Alan Trench, and several interviewees who were kind enough to read this for their helpful comments. Errors of fact and interpretation are mine. I would also like to thank seminar participants and interviewees for their time and discussion of the issues, the Nuffield Trust for supporting the work, and Kevin Woods for the whole idea of examining the way the EU’s adjacent powers are changing health services policy.

evidence for it, and an argument that policymakers across the health services of the UK would be wise to develop their skills at European Union politics and policy quickly, before the rules of the game are set by others.

This briefing lays out the mechanisms bringing the EU into health services policy and the reasons that the defenses member states erected have been inadequate, and then discusses the emerging opportunities and challenges for the NHS systems. The research has been supported by the Nuffield Trust, based on two seminars held under Chatham House Rule hosted by the Trust in July 2004 and preliminary interview-based research by the Constitution Unit and School of Public Policy, University College London. It outlines the various issues at stake in health services policy and in the consequent EU politics, including the diverse legal and organisational tools Brussels might bring to bear, and the responses of the different parts of the UK.

The first section describes the defences that the member states, including the UK, have constructed in order to preserve their autonomy and freedom of action in policy regarding health services. Like the famous Maginot line, the hard and fast defences created by the member states in the treaties have a serious flaw: while they prevent frontal attack, it is always possible to go around them. The second section describes how the EU, above all the European Court of Justice, has circumvented the Maginot line the states constructed, using the immensely important powers conferred on the EU as the guardian of the single market.

In other words, the European Union is already a major force in health services policy, one that is rapidly moving and changing. What specific opportunities and threats exist as a result? And what are the health services and governments of the UK doing to respond? The rest of the paper looks to the changing politics of EU health policy in order to sketch out the most important changes and the responses so far by the NHS and government of the UK. Part III discusses the politics of the issue in Brussels and Luxembourg, focusing on the sources of potential new policy in the Commission. Part IV addresses the responses of the various responsible parts of the United Kingdom to the growing importance of the EU. On one hand, it is encouraging: the Department of Health, the devolved bodies, and parts of the NHS itself have worked to develop information-gathering and lobbying skills adequate to formulate and carry out European strategies, or at least know what is happening. There are also small but established networks between the different individuals involved in EU health policy. Likewise, some of the major interest groups in health are developing their EU policy capacity, with offices in Brussels and attention to developments in EU policy. On the other hand, there is still considerable cause to worry: knowledge of events in EU health policy is still extremely patchy and even clearly functioning information pathways – such as the repeated warnings of the consequences of the Working Time Directive – do not necessarily have any impact in time.

Scott L. Greer
The Constitution Unit
School of Public Policy
University College London
s.greer@ucl.ac.uk

1. THE MAGINOT LINE

The formal health competencies² of the EU are comparatively weak and focused on high-level public health issues, joint campaigns, and, much more recently, shared problem-solving, benchmarking, and information-sharing. Looking at them alone would appear to justify the widespread view that the EU has little or nothing to do with health services. While implicitly health has never been excluded from treaty provisions pertaining to the single market, there were no serious health competencies for decades (Hervey 2002a, 2002b; Randall 2001). Health ministers had met since the 1970s, and there were some European actions such as a “Europe against Cancer” started in 1987 and a program against AIDS started in 1991. These focused on regulatory single market measures. The cancer program attempted to go beyond traditional regulatory methods (geared to the reduction of environmental carcinogens) by providing funding for research and health education. Such policy discussion and joint funding had little significance for the core of national health services.

The Single Europe Act (SEA) of 1986 began to change the situation with regard to health services by establishing authority to legislate on issues of health policy connected with the internal market. On one hand, this meant giving a push to the very sluggish process of professional degree recognition (started, in medicine, in 1975) so that there could be free movement of medical professionals across borders (Nichols 2004). On the other hand it also meant passing much regulation in order to mitigate potentially undesirable side-effects of the market and to prevent discrimination through regulation. This meant that the SEA included powers to legislate in occupational health.

The subsequent Maastricht Treaty on European Union introduced some health policy issues into the treaties. These were, it seems, introduced to strengthen the social character of the EU as a step on its road to union after the completion of the single market. It inserted article 129 (now part of art. 152), which provided that “the Community shall contribute towards a high level of human health protection by encouraging co-operation between

2. “Competency” is European jargon for a government’s right and power to do something.

Member States and, if necessary, lending support to their action” and which obliged the EU to take health protection into account in its activities generally. This meant that the “activities of the EU institutions are limited to co-ordination, and harmonisation of national laws is explicitly excluded from Community competence”. The European Council elaborated in 1993 that “public health as such, except where the Treaties provide otherwise, is the responsibility of the Member States” (Hervey 2002:26-7).

The Amsterdam Treaty of 1999 expanded the social dimension of the EU by incorporating the Social Charter (previously inserted as an appendix so that the UK could opt out) and trying generally to better integrate social concerns and citizens. It also came on the heels of the “mad cow” (BSE) crisis, which had damaged confidence in Europe’s health protection system. In health, this meant an elaborate new article 152 which integrates public health into all Community policies. It specifies a number of areas for Community action including blood and organ protection and states that “Community action...shall be directed towards improving public health preventing human illness and diseases, and obviating sources of danger to human health” (s. 1). The actual powers allocated to do this remain weak. Community action is largely restricted to fostering coordination and every section of the article has verbal formulas stressing the limits on the Community role. Even its strongest specified roles a regulatory task of standard-setting for blood and organs, is qualified by statements that say states can have higher standards and that its activities shall be “with” member states. It is not hard to imagine health gains from incorporating health concerns into all Community activity, but there is still not much of a health policy field. The strongest instrument available is a recommendation, which is far from the most powerful tool in EU law.

The proposed Constitution for Europe promises to extend the health competency further, offering a EU competency in public health shared with member states and justified by the real problems of controlling infectious diseases and public health risks at the member state level alone (Fidler 2003). Article 13.2 creates a shared competence in “common safety concerns in public health matters” (shared competencies, it appears, will not put ceilings on EU activity but will allow state activity). Article 16.1 establishes the European competency for “supporting, coordinating, or complementary” action over “protection and improvement of human health.” These are among the few identifiably new competencies. At least in theory other competencies are denied to the EU, and these are limited by the principle that the EU has only the powers conferred on it by the states and by the requirement that its actions must be “proportional” to the objectives of the constitution (art. 9). Member states have shown little desire for EU involvement in their health services (Jorens 2002; Hatzopoulos 2002:106).

Insofar as it is up to member states, that is, in the treaties and legislation, there is no important EU health services policy and not much other health policy. Rather, there is a duty to take health promotion seriously in internal market policymaking and coordinate some health policies, use of existing legal powers to reduce tobacco use (Hervey 2001), a right to coordinate aspects of public and occupational health, justified by the single market and largely irrelevant to the concerns of health services (save for when it regulates them!), and a European interest in certain concrete public health interventions. Indeed, one of the

greatest opportunities associated with the EU lies in such funding. Applications for funding, including regional development “structural funds” and many different grants for research and disease prevention, fall under this category of policies that might be useful for health services, but which can also be ignored. Its activities have largely been restricted to funding various disease-specific programs of education and research as well as broader investments in infrastructure; many health policy scholars will still say that EU health policy is still “all about public health.” Its most explicit decisions on health have been around cancer, AIDS, and tobacco in addition to use of its regulatory powers against environmental health threats. In other words, they are about public health (Randall 2001:95) and public health is the “Cinderella” of health politics. It is marginal, low budget, far from politically salient, often seen as preoccupied with drains, extremely complex, long-term, and in many EU states sclerotic or scarcely developed at all (Hunter 2003:17). Even the post-SARS establishment of a European centre for the control and prevention of infectious diseases is only “standard European networking. [It] will network centres, since the national centres are nodal points of networks of practitioners and experts. It will be to share data, working in parallel to make data comparable, and to more economically access global debates”.³ Such networks might matter, but need not.

3. Robert Madelin, Director General, DG Sanco. Remarks at European Policy Centre/Nuffield Trust seminar, Brussels 15 September 2004.

2. ENTER EUROPE

The EU impact on health services to date has been based on the internal market and has been driven primarily by the European Court of Justice. It is the jurists who spearheaded the drive around the defensive fortifications. This section identifies three major areas in which EU policies essentially intended to achieve ends in internal market policy proved able, often with a push from the European Court of Justice, to change the environment of health services. What they have in common is the ability to change the nature of health services and origins outside health policy debates. In each case the member states held true to their evident interest in not making EU health policy, and in each case some combination of regulatory legislation and the ECJ changed the resource environment of health policy.

The pre-eminent mechanism used by the Court is what Nickless calls the “translation of national legislation into ‘Euro-speak,’” i.e. the elimination of discrimination on the grounds of nationality, replacing references to states (as locations of services, as relevant professional communities) with the EU (Nickless 2002). This can be quite radical; for example, it means that structures for licensing practitioners or contracting them must not incorporate location as a value. For example, Luxembourg since the *Kohll* and *Decker* decisions (ECR [1998] I-1931 and ECR[1998] I-1831, respectively) has not been able to say it will reimburse for care in Luxembourg (and therefore presumptively quality-controlled by Luxembourg agencies); it must contract with providers from anywhere in the EU, and if it is to control quality to its own tastes then it must establish nondiscriminatory contracting procedures not linked to its territory. The second mechanism that the ECJ has used is expansive interpretation of terms, often according to implicit models of shift work that medical professionals strongly resist. This section catalogues the impact that the EU is having on the concrete work of the health services via unintended forms of spillover; above all the use of legislation without intended health content by the ECJ to influence health services policy. The section after that examines the Europeanised response by the players in health services to this uninvited Europeanisation.

Labour

In 1906, Rudyard Kipling addressed the students of Middlesex Hospital Medical School at their annual prize ceremony with a few stirring words about medicine. He told them that “It has long been decided that you have no working hours that anybody is bound to respect, and nothing except extreme bodily illness will excuse you.” He asked them, rhetorically: “Have you ever heard of any legislation to limit your output? Have you heard of any Bill for an eight hours’ day for doctors?”

The question remains rhetorical, but the answer has changed. By 2006 such a thing should be well established. One hundred years after Kipling spoke, health services will either have established or be implementing 48-hour limit on the hours anybody in the NHS, doctor, nurse, porter, or paramedic will work. This is because of the EU, specifically the Social Charter that Labour joined upon winning office in 1997 and its subsequent expansive interpretation by the European Court of Justice

The Working Time Directive (93/104/EEC) stated that “the completion of the internal market must lead to an improvement in the living and working conditions of workers... This process must result from an approximation of these conditions while the improvement is being maintained” (art 7). The Directive, in addition to discussion of holidays, both limits workers to an average of 48 hours a week, and requires that there be substantial daily rest periods. It exempts a number of sectors, predominantly in transport, but a 2000 amendment brought junior doctors into its scope, with application of the Directive phased in over five years from 2004, starting with a 58 hour per week limit on 1 August 2004 and dropping to a 48 hour limit in 2009 (Council Directive 2000/34/EC, 22 June).

The unexpected consequences of this legislation were born of judicial politics. The problem has emerged in the definition of working time. ECJ interpretations of the WTD have subsequently expanded the definition of working hours so as to sharpen its impact on health services. The two crucial cases for this are *Sindicato de Médicos de Asistencia Pública (SiMAP)* in 2000 (Case C-303/98, ECR I-7963) and *Jaeger* (in 2003; C-151/02, 9 October). The former case established that time spent asleep while on call is considered working time, and the latter that this meant the doctor, upon awakening, was eligible for immediate compensatory rest. Health services traditionally have long hours, and long hours on call when the employee is resting or asleep (often in special suites in the hospital, or even at home in some primary care systems). Reducing working hours has therefore serious knock-on effects for the structure of medical services.⁴ European health care systems could often only work because of long hours that, in various proportions, ensured out of hours coverage for primary care and adequate staffing for hospitals, albeit primarily of trainee and junior professionals who would bear the long hours. By reducing hours worked and the flexibility of the hours, the Working Time Directive will increase staffing shortages and difficulties overnight.

The UK House of Lords estimated that the directive would cost the NHS the equivalent of

4. This analysis of the consequences of WTD draws on analysis of interview data listed in the Appendix of (Greer 2004)

3700 junior doctors' work a year. In their submissions to a European Commission review The Dutch government estimated it would have to spend 100 million Euros on extra staff and Germany estimated that it would require more than a fifth more doctors at a cost of 1.75 billion Euros (Sheldon 2004). It also provokes some worries specific to individual systems; the UK, for example, has a private sector based on doctors working outside their NHS contracted hours. It is – still – not clear what will happen to this traditional bargain.

In turn, this will make many smaller facilities, particularly rural hospitals, unviable. Financially, if a hospital cannot combine on-call and shift time in a doctor's day (the option precluded by the combination of *SiMAP* and *Jaeger*) the hospital must hire more doctors, and that might force it to close. Further, there will be consequences for medical quality. There is a consensus that for safety reasons doctors should only carry procedures that they perform regularly and in sufficient numbers; otherwise they get out of practice. If the WTD requires that a small hospital double the number of specialists, it can create a safety threat since the WTD will not double the number of a given procedure that must be carried out. As a result, smaller hospitals, particularly rural ones, will become much more expensive and reduce the range of services. Preparation for the WTD as already led to a wrenching series of debates about local hospital closures. It will also change the nature of medical training in some countries, such as the UK, which traditionally have long periods of training; since much medical training is clinical, i.e. performed under supervision and on real patients, reducing the hours worked by trainee doctors reduces the hours they spend receiving education. Without a radical restructuring of medical education, and probably addition of years to it, there is a considerable risk that the WTD will produce a generation of doctors with inferior skills (see the contributions by the Royal Colleges of Nursing, Physicians, Physicians-Edinburgh, and Surgeons-Edinburgh to the UK House of Lords European Union Committee's Response to the European Commission's Review, 8 April 2004). The ECJ's influence, meanwhile, continues to grow; in an October decision, the ECJ applied the WTD to ambulance staff, who now will have to individually opt out of the 48-hour limit (Watson 2004).

There is a good chance that, in response to these problems, the member states will force through a clarification of rest as part of a larger deal modifying the WTD. At the time of writing, a redefinition of rest (essentially undoing *SiMAP* and *Jaeger*) is likely to be included in an amendment (see the Commission proposal of September 2004, COM(2004)607). The issue is being discussed at a very high political level, and has been linked in classic European fashion with a range of other WTD debates including the UK's opt-outs, and like everything else in the discussion is liable to some sort of change as states and the Commission try to work out a package deal.

Professionals

One of the key freedoms of the EU is labour mobility (freedom of movement, and, increasingly establishment); since the beginning of the Common Market there have been treaty statements and policies intended to make Europe essentially one labour market with no impediments to the right of citizens of the different countries to move back and forth to work.

In health this has meant that EU mutual recognition law has, since 1975, slowly extended across medicine (being consolidated by directive 93/16/EEC)(Nichols 2004). While there are legally interesting issues such as the fate of professionals educated outside the EU and licensed in a member state, the essential logic of mutual recognition, and the Court, is that adequate common standards mean a doctor is a doctor and a nurse is a nurse. Core training standards in the legislation underpin mutual recognition. The principle of nondiscrimination thus means that it cannot be assumed that a national of, or person educated in, a given country is better qualified or better than a person educated elsewhere in the EU who is licensed by the authorities of the state.

The impact on health services staffing is still limited. There is little cross-national medical mobility, EU or no, and due to the prominence of English much of what there is goes to the UK (Jakubowski and Hess 2004). Workforce planning is, it appears, only more difficult when it affects countries that share a language and often more. When the Republic of Ireland began to pay certain doctors more in 2001, it was, according to a high-level medical officer interviewed in Belfast (Jan. 2002), only Northern Ireland that lost significant numbers of doctors to the higher-paid southern positions- and those doctors were not usually Northern Irish Protestants, either. The only major medical profession without freedom of establishment is pharmacy, since pharmacies are crucial (and politically influential) in a number of states and are both protected and centrally allocated (Hervey 2002:87 n 95).

More important is the symbolic and possibly real impact of changing the guarantees of medical quality. The ECJ, resting on decades of policies intended to promote medical mutual recognition of degrees, has not shown any interest in the idea that standards of medical quality are anything other than commensurable and equally high across the EU. It would be very surprising if either assumption held true (Mossialos and McKee 2004; Nickless 2001:82). The elites of medicine, who are unfailingly influential in health policy communities, tend to be faculty of leading teaching hospitals, and they also tend to exercise significant influence over professional qualifications as judges or as self-governing professions. Relinquishing power over medical training and licensing is a direct blow to their power over the system and over definitions of good quality, medicine, and practice; regardless of its practical effects, it undermines people who are always among the elites of a country's medicine. At the same time, though, the UK is probably and is likely to remain a net beneficiary; professionals are more likely to speak English than other EU languages save their own, and the UK NHS is short enough of professional staff to be already employing many of them.

This dynamic accords with the basic logic of EU policy: Labour mobility includes professional mobility. Qualifications regimes subject to EU law and the requirement of nondiscrimination extend far beyond medical professions, including licensing to run temporary employment agencies or become a hairdresser. Given the large part of the economy that they cover, and their abundant potential as market restrictions, they were a natural target for market-builders. Furthermore, some health systems take considerable advantage of it, given significant differences in staffing needs and training across Europe.

The UK in particular is ill-placed to complain about crossborder professional mobility, given immigration professionals' crucial role in the NHS and in its present capacity expansion.⁵

Patients

Discrimination on the basis of citizenship in a given member state is very difficult to justify in EU law, running contrary as it does to the powerful legal principle of nondiscrimination, one or more of the basic (economic) freedoms of the EU, or the overall thrust of integration. For some decades now the ECJ has been chipping away at the right of states to limit access to their welfare states, starting with a series of decisions promoting access to social security for workers and gradually broadening out to include general access (Weatherill and Beaumont 1999:620-714). This has taken place in health, although member states have sought to limit crossborder usage in order to limit its potential for health tourism (Hervey 1998:147-50).

The crucial decisions are *Kohll* and *Decker*, both of which came out of Luxembourg. In both cases a citizen of Luxembourg used a service in another EU country and sought reimbursement in Luxembourg. The Court ruled that this is a right under EU treaty law. Given that the decisions interpret treaty law, they are very difficult for member states to modify or overturn with legislation. Their consequences could be dramatic, and not just because access to services had not heretofore been an issue for the EU. It should become impossible, for example, to use Luxembourg-based regulation to ensure that the Luxembourg tax money is spent well if the money can be spent outside Luxembourg. Value for money controls would have to be based on the list of approved suppliers, which could not be territorially discriminatory, rather than on establishment in Luxembourg. It also opens up a number of issues: which tariffs do states pay for crossborder treatment? What justifies crossborder treatment? How do the two interact: how long should a waiting list be before the patient can go abroad and bill the home system for the full cost of a higher tariff rather than just the reimbursement offered by the home system? What else justifies treatment abroad? What happens to systems (such as Scotland) that are not based on reimbursement? Who pays for travel costs if patients go abroad? What exactly does the Court mean when it suggests that member states can limit patient mobility in the interests of preserving financial balance? Answering these and other questions – backfilling *Kohll* and *Decker* – will almost surely be the basis of the extensive and complex EU health jurisprudence that law students will have to learn in ten years.

Crossborder patient mobility offers some potential for useful new policies in health care; it could make it easier and more likely that states collaborate in centralising very high-end treatment in one or two centres. But it poses challenges to budgets and the structure of health politics in most countries. Governments, naturally, are often disturbed by the prospect of citizens comparison-shopping health systems (sometime in the future, though,

5. Policymakers are well aware of the potential recruitment, as well as its occasionally amusing requirements. Consider the disclosure in *Health Service Journal* that the Department of Health is in discussions with Tesco supermarkets about a deal to have Tesco hire the spouses of the Polish doctors it is recruiting (Clews 2004) or the regular newspaper stories about NHS courses that teach newly arrived professionals the various regional dialect words of the UK.

citizens might object to cost-cutting governments that start trying to send them to send the to low-cost providers halfway across the continent). It poses administrative problems to do with reimbursement and nonterritorial regulation. It poses cost control problems and potential difficulties with facilities near borders that either attract more patients than expected or that suddenly lose patients. Finally, in some political systems the issue of overseas treatment is a political football; in England the government, concerned to demonstrate the benefits of the NHS, points to its pragmatic willingness to send patients abroad if that is “what works” while the Conservative opposition and press highlight the superior treatment and lower waiting lists “in Europe” (Greer 2004).

On a different, emotionally charged level, the ECJ has rather dramatically interfered in a major issue in medicine, namely responsibility for patients and quality within and between professions. The issue is the basis on which a national system may refuse to pay for a treatment available elsewhere (at all, or with a shorter waiting time). The ECJ, in a decision that runs contrary to the highly local nature of medicine, had to define reasonable treatment and ruled in *Geraets-Smits and Peerbooms* (ECR [1002] I-05473) that it would be discriminatory for the Dutch system to authorise procedures on the basis of Dutch medical opinion. Rather, in an example of Nickless’ “translation into Euro-speak,” it argued that the basis of decisions would be discriminatory if it were simply Dutch; it had to be at least European (Nickless 2002:73). For professional communities that value their autonomy and regard their standards highly, this often looks like needless and possibly dangerous levelling down (Mossialos and McKee 2004:102).

The immediate headaches created by these rulings are not as great as those created by the Working Time Directive, even if they symbolically strike just as hard. The absolute numbers of patients will probably not be great⁶ and appears to be driven primarily by proximity or interest in exotic treatments. There are many reasons why patients will not choose to cross borders. Some are obvious, such as differences of language and traditions of patient care. In fact, though, patients generally remain within medical referral networks of 5-10 doctors and practice variations are very local (Sciences 1998). Medicine is a high-stakes activity that requires a high degree of trust and involves significant uncertainty, and given the difficulty of producing reliable outcomes measures that tally with patient perceptions, the obvious choice in almost all circumstances is to work with the doctor one knows. Furthermore, tiny differences in medical treatment and its interaction with other variables can mean that crossborder treatment is not as good; for some reason, anecdotal evidence suggests that orthopaedic treatments in one country often have negative side effects on patients from other countries. This means that outside border areas with significant crossborder patient flows, or limited, sunny, retirement havens, health systems probably need not worry too much (and if they do find themselves saddled with large, expensive patient flows, the ECJ has said that preserving the financial balance of welfare states is an acceptable justification for restrictions; see for example *Kohll*).

6. With the exception of Spain, which is expressing concern at the large numbers of German and British retirees using its health services. The problem is not so much reimbursements (although there are questions about their adequacy, given the complexities of language and chronic ailments); it is rather than Germany, Britain, and other northern countries reimburse Madrid, but the money seems not to find its way through the Spanish regional health systems to the actual providers.

It does risk creating problems of equity. Insofar as crossborder medical treatment is actually better, we can reasonably assume that it will be the educated and organisationally literate who get it, rather than the less advantaged populations. The inverse care law specifies that those who need care most will get it least in good part because those who need care most lack the bureaucratic literacy to get it (Tudor Hart 1971). If that dynamic works in the NHS, it is hard to imagine the problem getting anything other than worse when it is a question of going to France for a hip replacement.

The real problem lies not in the actual mobility of patients (although if the system's finances are fragile enough, that might cause problems). It lies in the adjustments that the system might be required to make, in terms of priorities and in terms of administration. The administrative problems are to do with setting up systems that cope with patient mobility, avoid subsidising it needlessly, and cope with its impact on workloads; there is a system in place already, but increases in the scale of patient mobility might prove a challenge. In terms of priorities, the chief question is what will become of waiting lists. As a participant in a seminar noted, there are a few basic ways governments can ration services to patients other than by professional: by limiting the list of services covered, by requiring co-payments, or by waiting lists (also Klein, Day, and Redmayne 1996). The ECJ seems bothered by only waiting lists, and inclined to create a standard of a "reasonable" delay after which a patient can seek alternate treatment. "This scares NHS managers" noted a NHS EU liason in October 2004. "The real significance of the Court's thinking is that it has no problem with people paying more or a national government restricting services. What they do have a problem with is people waiting longer than they as lawyers think people should wait." explained a UK official in July 2004. At the time of writing, there is a case referred from the UK courts to the ECJ which should settle, with possibly momentous effects, the issue of what constitutes the 'undue delay' that permits patients to seek alternate treatment on their home system's tab (*Secretary of State for Health v. Yvonne Watts*, Royal Courts of Justice, C1/2003/2399). If it sets a standard for waiting times, it could create problems for the whole NHS (and crises for the Welsh system in particular, born of the fact that Wales has set different priorities and chosen explicitly not to focus on waiting lists, and instead to focus on other, longer-term health policies). That decision, taken – amidst much criticism – by the National Assembly, could be under serious threat if a standard emerges of "reasonable" time for waiting.

Purchasing

Health services do not just depend on the presence and movements of patients and professionals. They also buy vast quantities of goods and services, from real estate and cleaning products to pharmaceuticals and medical devices. These are all subject to EU law in at least two ways: because of EU restrictions on ways of conducting public purchasing, and because of EU harmonisation of standards that restricts the scope of member state control over what can be sold to their health services. For reasons of space and specificity to health this report focuses on the latter.

The regulation of devices and pharmaceuticals matters because of the large (and rapidly increasing) amount of money at stake as well as the interest of this high-technology, research-dependent industry in which Europe has traditionally done well. States are already juggling two sets of incentives. On one hand they have an incentive to lower drugs costs to national budgets (there are thousands of drugs on sale in Europe, even if the usefulness and cost-effectiveness of many are debatable). On the other, they generally want to assist their biotechnology and drug industries. Drugs and to a lesser extent medical devices firms have been favourite national champions of member states; to this day France is highly reluctant to see “its” drug firms leave French ownership.

EU intervention in medical purchasing dates back to a 1965 directive (65/65/EEC) inspired by the thalidomide scandal. It simply required member states to make sure no medical products were sold without the approval of an appropriate regulatory body. A group of directives in 1989-1990 provided detailed regulation of medicines as part of the internal market legislation connected with the drive to the 1992 single market and since then there have been (Hervey 2002:89-91).

This single market legislation all simply classifies the sale of medical devices as part of the internal market and harmonises regulatory standards in order to facilitate protection and crossborder sales. The concept of harmonisation is that it “establish[es] a regime that breaks down market-partitioning national rules and replaces them with a Community system that aims to accommodate diverse tradition within a flexible yet essentially unified framework” (Weatherill and Beaumont 1999:555). In medical devices it has provoked a debate about whether the EU has ignored major variations in the standards of the regulators, or set the bar too low and thereby allowed the introduction of dangerous or ineffective technologies. In other words, pharmaceuticals and medical devices might be sold to the ostensibly protected field of medicine, but their sale means that they are on the market and there is very little justification for “market-partitioning devices” in EU law. The result has been the creation of an EU market in pharmaceuticals and to a lesser extent in the very diverse category of medical devices (Randall 2001:68-94).

This combination of a need for some defensible basis for the harmonisation – why should regulations be set at the level they are set? – combines with the logic of removing barriers. It also comes alongside a major international trend towards improved technology assessment, driven by professional leaders and health funders worried about value for money and the hazards of political involvement in rationing (Walshe 2003). And finally, it comes from the fact that pharmaceuticals and medical device companies, which have to bear much of the costs of clinical trials and regulatory applications, intensely dislike the spread of new drugs licensing regimes and would prefer to centralise it on a continent-wide level rather than cope with multiple regulatory regimes such as the three of the UK. The response from the EU, saddled with the need to justify standards it must set in order to make the market function, has been the establishment of the European Medicines Evaluation Agency in London in 1995, as another EU-sponsored network centre (Regulation 2309/93/EC). It is obligatory for some products based on biotechnology to be authorised by it before sale in the EU, but otherwise voluntary. Hervey points out that the number of submissions and such authorisations grows steadily (Hervey 2002:90 n 122).

This is partly because voluntary submission, while expensive and often irritating to the firms, builds up their expertise in influencing the regulators and, if done with good grace, might improve their standing and credibility with the regulators, whether they are the EMEA or the All Wales Medicines Strategy Group. Good relations and skills developed through voluntary submission now can, therefore, be a good investment should the regulator gain in power later. The result of both drug firms' incentive to support an EU-wide standard and their incentive to be nice to regulators is that now there is an EU role in technology assessment as a consequence of the EU development of the single market in medical products.

Summary

If something got into a health service, it came via a market. The result is that EU health systems have lost considerable control over their ability to shape their workforce and its quality, being reduced instead to a lowest common denominator of professional qualification due to the developing EU qualifications regime; that they have been forced to start a major process of restructuring services, training, and work patterns in response to the Working Time Directive; and they are operating in a regulated commercial environment that reduces their ability to design services and financing as they traditionally have done. Even when the immediate practical impact is limited, as with patient movement across borders, the changes can require mind-bending administrative reorganisation, challenge fundamental parts of the system (such as rationing by waiting) and be deeply symbolically offensive to those involved in running the health systems: the internal market requires assumptions of commensurability and common standards that many professionals might doubt. This process of Europeanisation is not so different from many other sectors of European society, and this conflict over the ability of professions to control their environment is hardly unprecedented either. The differences are that member states explicitly refused to submit their health systems to this kind of treatment and that it was, rather, driven by internal market concerns or the unintended outcomes of single market legislation.

3. RESPONSES IN THE EU

The European Court of Justice might have led the way into health by applying internal market provisions of the treaties to health and by interpreting legislation in its distinctive manner, but there are now other parts of the EU political system being drawn into health policy. The result is that there are so far three broad EU responses running in parallel, with considerable potential for duplication mitigated by the minimal likelihood that all of them will continue to matter.

Much of this diversity of response is simple pragmatism: the member states are, by and large, not interested in duplication, but are willing to try out the variety of policy tools offered by various parts of the Commission in the hopes of finding a mechanism that will preserve their control over areas they want to control, lend some predictability to the EU's heretofore highly disruptive interventions, and develop the benefits of the EU in health. The Commission, fragmented, diverse, and internally competitive, is happy to oblige with a range of policy tools. The European Commission is a small organisation that primarily writes legislation within the scope of the Treaties (or, often, on the edges of what the Treaties might permit) and attempts to enforce its integration into state laws and policy; it also has some sections (agriculture, regional aid) that allocate substantial funds to member states, but which implement very little on their own. In other words, the Commission is primarily a generator of regulatory legislation (Majone 1996), regulatory proposals and pan-European networks.

Each of the Commission's "ministries" – Directorate Generals (DGs) – has a different set of powers, stemming from different Treaty sections authorising or blocking EU action and from existing law and legislation. These vary, creating marked differences in the approaches, powers, and likely policy consequences of having one DG or another involved in policy. Right now, there are three DGs with an interest in health, each one formulating proposals that would allow it to pursue its aims and increase its role in health.

Commissioners' interest in making a mark, common to politicians of all kinds, mean that a large and largely non-EU policy area such as health will naturally attract their interest. Furthermore, the sudden salience of the EU in health policy, particularly with the ECJ

decisions on the Working Time Directive, mean member states demand some more predictability, accountability, and coherence in EU health policy.

DG Health and Consumer Protection, public health and the High Level Working Group

The first DG at work is DG Health and Consumer Protection, known as DG Sanco. DG Sanco has a problem in health services policy: it is the guardian of the EU's formal health competencies, and, as discussed above, those are feeble indeed. Its competencies to date are focused on public health, particularly the blood and tissue responsibilities that came with the fallout from BSE. All of the states' limitations on health services policy apply to it; it is directly facing the Maginot line. It therefore is thrown onto the second-best technique for expansion of EU powers. The best technique, as argued above, is the use of internal market regulatory powers; this plays to the strengths of the EU as an essentially regulatory creature. The second-best technique, however, is to attempt to develop EU networks and funding arrangements that will create clienteles within the member states while increasingly "Europeanising" the activity. This has been the case with, for example, research and development. In the case of DG Sanco, it is attempting to build EU-wide networks around infectious disease and public health, and, more vaguely, around European networks for medical research and treatment. It is the "standard European networking" discussed in the case of the Stockholm centre, which it sponsors.

Finally, there is the option of trying to influence other DGs, despite the fact that they, like government departments anywhere, tend to have their own policy networks and resent another DG piling into their work. DG Sanco has a tool with which to try to do this; the Amsterdam treaty provision obliging the EU to take health into account in all of its work creates a niche for Health Impact Assessment of all policies, and the power to assess is in the hands of DG Sanco although this author has not been able to find anybody in the UK or Brussels who thinks that its health impact assessment has had an impact on policy.

DG Sanco did, though, have a brief role as the leader of the EU's health policy in a response to the patient mobility decisions by the ECJ. These decisions worried member states, for the administrative headaches they could create, and for the important legal and policy implications in the future. Their response was to start a High Level Reflection on the issue of EU health policy, with a focus on patient mobility issues. DG Sanco ran this group, which concluded with a number of recommendations. One such recommendation was the creation of a High Level Working Group to sort out issues of patient mobility and to develop a coherent, perhaps legislative response to the challenges that would allow member states to formulate sophisticated policies appropriate to health and manage their implementation. This history made it, as one interviewee noted, a "linear descendant" of the ECJ decisions. The High Level Working Group has now been constituted, although its political sensitivity has led to efforts to avoid publicly discussing what it is doing. This line of activity, however, looks like it is being overridden by a very different approach, led by a very different group of actors.

DG Internal Market, the ECJ, and the Services Directive

The second DG at work in health is DG Internal Market. This is the DG responsible for the preservation and expansion of the EU internal market; its *raison d'être* is the identification of areas of the European economy that are not integrated into a fully nondiscriminatory regime, and their integration into one. The strength of this DG is its control over the proposing and writing of internal market legislation. The Treaty, and events in developing EU law, provide this DG with far more authority to promote powerful new legislation than most of the others, since this DG controls the internal market that was virtually the only focus of the EU for the decade until 1992 and which is now well established as one of its main activities. It also helps that the ECJ's decisions, which almost always go in favour of greater expansion of the internal market (and, of course, the role of EU law), tend to back up internal market legislation and its more expansionist interpretations. Its tool in health is the "Services Directive" (proposed Directive on Services of General Interest; green paper May 2003, COM(2003)270, and the less obviously radical white paper of May 2004, COM(2004)374). This rightly caused a major scare in health policy circles during 2004 and its passage still could reshape UK health policy more radically than any government since Thatcher.

The background of the Services Directive lies in the EU's development of regulatory schemes for a variety of policy areas that were mostly once provided by the state, which are tied together by the need for some principles of social solidarity such as a universal service obligation. The logic is that such services of general interest can be improved by the introduction of EU-wide competition and market forces, but that they must be tamed by regulations intended to preserve social benefits such as access for unprofitable clients. The proposed Directive consolidates the different sectoral regulations for these utilities into a broad framework that can be applied to the whole category.

The interest of the proposal, known as the "Services Directive," is that its opening and closing sections clearly include health in this category, even if the middle sections of the white paper stick to familiar grounds like telecommunications. "They are not being honest, it is clearly included" explained an EU interviewee in June 2004. "That is why the member states were so furious when [Commissioner] Bolkestein came up with the Services Directive- it subsumed these complex issues...The health services would prefer to have the Commission deal with the ECJ under the High Level group, with discussion, with time to work out the complex issues, rather than whacking it all into Article 23...They checkmated DG Sanco, which tried to block it. Sanco knew from running the High Level Working Group how the member states would react" explained the NHS staffer, in October 2004. "If health services are to be regarded as single market services, every single market issue would have to be scanned- it would be a sea-change in the department of health" explained a UK Department of Health official in August 2001. In other words, it would be the apotheosis of the translation of health services into "Euro-speak," requiring that the NHS not be run in a way that discriminated against contracted service providers from elsewhere (and, on the plus side, making it hard for other member states to keep the NHS, currently expanding rapidly, from poaching their resources and services).

The Services directive, at the time of writing, is before the Commissioners, and being dealt with at the highest political levels, at least in the UK. “Whacking [health care] into Article 23”, regulating health like posts or telecommunications, would shake EU health systems, quickly, like little else ever could. If the political opposition is too much, directives at this point tend to simply subside into invisibility rather than go to a vote that they will lose (such is the present, and perhaps permanent, fate of the directive on temporary employment).

DG Employment and Social Affairs, the Open Method of Coordination, and benchmarking

The third DG and policy strategy at work is Employment and Social Affairs, the DG responsible for the WTD but also generally for harmonising employment and protecting the “European social model.” This DG has developed its remit by building up a definition of the social model that runs beyond its original responsibility for affairs related to employment regulation, and it includes good health and a right to treatment as aspects of the social model it sees its job as defending. This DG has less room for legislation than DG Internal Market, but it also also experience and command of the Open Method of Coordination (OMC). The OMC is a process of peer evaluation and benchmarking in which a permanent committee of civil servants from the different member states meet and agree an action plan, related to individual member states’ action plans, which will provide a basis for the development of indicators, exchange of policy ideas, and a form of peer pressure on states to solve their problems, whether those are unsustainable financing or poor control of communicable diseases. The OMC method, steered by DG Employment and Social Affairs, is already at work in pensions policy, employment, and social insurance, attempting to develop cross-European performance indicators and comparing notes to improve performance without using the blunt tool of EU “hard law.” At present, the Social Policy Committee has been constituted, with its stable list of civil service members (the UK representative comes from the Department of Health). They are working on its plan, which will suggest the activities that will be of interest to it.

It is easy to be negative about the OMC, or to justify it in wholly negative ways. The OMC, from the point of established health systems that would like to be left alone, has one enormous advantage over all other forms of EU intervention: it is essentially judge-proof. In EU law there is no way – at least yet – that OMC commitments and activities can be made justiciable. Its other advantage, and its disadvantage from the point of those who would like to see EU-level policy, is that it might be judge-proof meaningfulness. Neither practitioners nor academics are willing to give it unqualified approval as a meaningful policy instrument. Voluntary self-regulation and “peer pressure”, the basis of the OMC, are not, after all, known as the most effective ways to get things done (and their current poor record in shaping member states’ compliance with the Euro’s growth and stability requirements suggests that they might increase transparency without putting sufficient pressure on states to achieve).

There could be scope for this information-gathering exercise to interact with existing policy – for example, a Europe-wide quality indicator developed as part of the OMC might be used by patients to promote their own mobility by going to a superior hospital in France or Denmark – something they might be able to then bill to their PCT, LHB, or Health Board.

This prospect should interest any chief executive in the UK, although the search for useful benchmarking measures in other fields such as pensions, or in the health policies of other countries, has not been easy and the problems and implicit value judgements of indicators in health are well known.

But it is not justified to end the OMC discussion on a downbeat. There is real value to a “soft-law,” comparative approach that allows the member states to identify their problems; even if all the OMC process generates is comparative data, that will be useful for policy advocates and those who seek evidence for policy arguments. The OMC (like the High Level Working Group) also permits a form of European integration not driven by courts and markets, but one sensitive to the interests of the important systems and imperfect markets at stake.

The future: policy choices and an EU of 25

All three mechanisms are currently running in parallel, with the Social Policy Committee setting up OMC, the Services Directive being discussed in the Council, and the High Level Working Group still working – while member states also discuss WTD revisions, the ECJ considers *Watts*, and DG Sanco continues to prospect in public health for a larger EU role. They are patently duplicative, and each policy option encodes different values, and so it is highly unlikely that they will all survive as meaningful parts of EU health policy. Which ones will survive, and how they will interrelate is at the time of writing extremely unclear, and the politics are still very much open to influence. The High Level Working Group approach might have lost out to the Services Directive in internal Commission politics, and the OMC might supplant both, but that is truly still to be determined. The EU’s health policy is all to play for – but it is unlikely to stay that way for long.

At the same time, though, the basic politics underlying the member states are likely to be radically shaped by enlargement: the recent arrival in the EU of Estonia, Latvia, Lithuania, Poland, the Czech Republic, Slovakia, Hungary, Slovenia, Greek-speaking Cyprus, and Malta, creating a Union of 25 states. The impact of these new states’ arrival on health policy could be dramatic, changing the dynamics of a game so far largely played by established, rich, states trying to defend their health systems against the unexpected problems created by the ECJ and Commission.

The relative poverty of the new accession countries should have an important influence on their views. Various policy analysts in the UK might worry about different issues – about the impact on quality and clinical governance of cross-border professional mobility, or about potential threats to such cross-border mobility (a major issue, given the UK’s dearth of professionals). Spanish policymakers in the regions might worry that they fail to see the reimbursements Germany and the UK send to Madrid for their pensioners’ treatments. But the basic viability of the health systems of the older EU-15 under EU health policy is much less in doubt than the systems of the new accession states. On one hand, professional mobility is very likely to denude them of professionals who are more than welcomed by the understaffed and (comparatively) well-paying systems of the western states. On the other hand, confusion surrounding the question of patient mobility also contains serious threats.

While the substance of ECJ jurisprudence appears to have run against it, there is still a chance that Lithuania could find itself paying German tariffs for treatments Lithuanian patients get when they tire of waiting for treatment at home (and that the waiting in Lithuania might be because so many of the doctors were recruited by the UK).

Their size and limited policy capacity should also matter. There are, for all practical purposes, only two large accession countries: Poland and Hungary. Some are tiny; Malta has a population only slightly larger than the London Borough of Barnet. This limitation of their policy capacity could cut in two different ways. On one hand, it means that they will not play as much of a role in many EU debates as older and better established states; a Cyprus or Slovenia will not be able to spare many civil servants to work out the consequences of various proposals for their health systems. On the other, it also means that they already sometimes see the Commission and the EU in general as an attractive partner in developing their services, particularly in the management of more plural and often insurance-based systems. This creates more of a market for the network-building efforts associated with DG Sanco, as well as an interest in aid (health is to be included in the next round of structural funds, i.e. development aid within the EU). It could change the dynamics and importance of the OMC Health and Care of the Elderly, and of the High Level Working Group. Learning need not, of course, be uni-directional; London NHS interviewees were pleased with some of the techniques they learned from Slovak partners.

The result is that in addition to the pre-accession debates about the best way to regain control of the EU health agenda from the Court, there are now new pressures for an EU health policy, whether to deal with professional and patient movements or to help the recently, radically, reformed systems of the former Communist member states, achieve their highest level of functioning. The policy that can offer the greatest degree of useful best practice diffusion (making the best of Europeanisation), harnessed to considerable member state control over health services, would probably be the one most likely to win if health ministers have a say in it.

4. THE TROUBLE WITH DEVOLUTION

These dynamics – the ECJ and developing policy – will shape the legal, economic, and political environment of health services from Donegal to Larnaca and from Cadíz to Oulu. Member states are able to respond to them with this variety of policy tools, in a complex dance between the different coalitions of states and different institutions of the EU. The greater problem, though, is to be found in Northern Ireland, Scotland, and Wales, all of which are in structural danger of losing some considerable part of their recently acquired health powers (Greer forthcoming (2005). This is one of the great surprises- and important surprises- of the last ten years of European politics: Europeanisation can be very bad for regional and devolved politics and policy.

There was, in the early 1990s, a flourish of regional enthusiasm for the EU. A combination of structural funds programmes that channelled EU money to regions, regional representation won at Maastricht (in the form of the Committee of the Regions and the right for regional governments to represent member states), and the seeming rise of regional government across the Union gave some credence to hopes of a “Europe of the regions”(perhaps the best indicator is that academics studying the continent apparently managed to produce more than 4000 publications containing that phrase! Kohler-Koch 2000).

The reality has proved rather different, at least on the level of practical policy. There is no Europe of the Regions. Rather, there is what there always was: a Europe of the member states represented in the Council, and able to determine the fate of Commission proposals and able to legislate to reverse much of what the ECJ did. There is simply no credible argument that Scotland (population c. 5 million) or North Rhine-Westphalia (population c. 17.5 million) have anywhere near the power of Malta (population c. 400,000). Malta has a Commissioner and Council votes; Scotland has neither.

This means that the regional governments tend to be, if anything, the losers in European policy. The problem is that the EU can consistently take away or seriously dilute regional competencies. Agriculture is in constitutional texts largely or wholly a regional power in many EU states, but that is a rather academic since the EU dominates agricultural policy

and finance, and it is member states that send their representatives to determine it in Brussels. Health, likewise, is generally a regional competency in Europe, and is in the UK a particularly strongly regionalised competency, with the Scottish NHS among the least constrained devolved health systems in the world (Greer 2004). This degree of devolution, though, is obviously constrained by the ECJ (and the Working Time Directive is one of the factors precipitating the ongoing Scottish and Northern Irish crises over hospital closures). And all three of the major EU responses- the High Level Working Group, internal market legislation, and the Open Method of Coordination- are based on member states voting to establish the mechanisms and then on member state representation and political influence.

In most states and policy areas, the result has been the regional powers vanishing up to the EU level. What Barcelona used to govern is now subject not to Catalan decisionmakers, but rather to Catalan decisionmakers working within a framework settled by Madrid – and Athens, Helsinki, Vienna and Dublin (Brugué, Gomà, and Subirats 1997). It is not a zero-sum reduction in the power of regions – it is, rather, the development of complex multi-level governance – but it certainly reduces the autonomy of regional governments and their ability to be accountable to their populations for what happens. Furthermore, it can create considerable space for policy breakdowns when member states agree a policy that regions find difficult or impossible to implement.⁷ It has created serious problems for countries with conflictual relations between the central state and the regions such as Spain, and has rewarded those which can coordinate so as to best represent regions as well as the central state, such as the UK to date and Germany (Börzel 2002).

The structural problem for all European regions with health competencies is simple. They are not *necessarily* informed and they are not *necessarily* represented.⁸ They can lobby directly in Brussels, one of the world's most-lobbied cities, but that is expensive and there are many conflicting demands on their representation.⁹ They can gather information as well, but some of the best and most politically sensitive information is restricted to member states. The result is that the most successful regional strategy – and one that both Scotland and Wales have been using in general since devolution (Jeffery 2005 (forthcoming)) – is to focus their efforts on becoming integrated with the Whitehall line whenever possible, so that the regions and London can work in tandem to promote their (considerable) shared interests.

The problem, though, remains. Northern Ireland, Scotland, and Wales – and Flanders, Catalonia, and Bavaria – are all subject to an increasingly important EU policymaking sphere in which they structurally tend to be poorly informed and poorly represented. They labour here under a disadvantage relative to the member states, but must nevertheless comply with EU policy. Poor coordination and cooperation in the relations between EU

7. Spain has had several incidents where the Basque Country implements a divergent form of a policy- and then Madrid is obliged to defend a Basque policy it does not support at the ECJ.

8. Save in Belgium and to a much lesser extent in Germany; when a regional competency (such as education) comes up in the EU, the Belgian regions agree a position and send one of their ministers. The Belgian central state has no role in most education policy on the regional level- or, importantly, on the EU level.

9. The Scottish Executive, proprietor of the largest, oldest, and most sophisticated UK devolved office in Brussels, has a list of priority areas that is focused on the economy and does not mention health at all.

institutions, member state, and region produce bad policy, bad implementation, bad feelings, and greater diminution of regional autonomy than need happen (Hooghe and Marks 2001:77-78; Subirats forthcoming). Getting the central-regional relationship right is therefore crucial.

Member states have problems with uninvited, court-driven Europeanisation and are struggling to master the complex European politics that have emerged in its wake. Devolved governments should pay more attention and work harder, because they lack even the guaranteed participation in decisionmaking of member states.

5. RESPONSES IN THE UK

The previous sections have documented that the development of EU policies poses the most significant new challenges to the NHS and that it is a rapidly moving and changing area with a great deal currently at stake. What are UK policymakers and health services doing to respond?

The interest groups are there; the unions (UNISON and GMB), RCN and BMA have all had Brussels offices for years, large ones in the cases of the unions and small for the two professional organisations, and are able to coordinate their lobbying across levels in European style – coordinating, for example, negotiations about the WTD with the Agenda for Change pay negotiations and doctors contracts of the last three years. It is likely that other interest groups will develop their EU operations. Policy advocates “shoot where the ducks are” and if they see the possibility of getting their policy through via the EU, they will go there (Richardson 1993:89-92).

In terms of representing themselves within the EU, though, what are the UK governments and NHS systems doing? There are responses within Whitehall, Belfast, Cardiff Bay, Holyrood, and the NHS itself. They are working to represent the institutional interests of the health systems more effectively, but it appears that they have a great deal to do to Europeanise what is a traditionally insular (literally) set of health systems.

Whitehall

The problem facing the Department of Health is not dissimilar to the ones faced by most other departments at some time in the history of the EU, and it can benefit from the developed British “model” of EU relationships, one which prizes close coordination, the development and pursuit of a consistent line, and a relatively high degree of centralisation via the Cabinet Office and UKREP, the UK’s diplomatic representation at the EU.

The International Branch of the Department of Health is small. It has about 20 people, not all of whom are predominantly concerned with the EU. This is partly intentional, based on

an analysis of what the Department can and cannot offer. It cannot offer specialised, integrated, EU representation capable of sharing intelligence across the whole range of EU policies and making complex deals; that is the responsibility of UKREP and the European desk of the Cabinet Office, especially the latter's health desk officer. It also need not replicate the skills found in the Department and the old Executive in Leeds, in areas such as finance and personnel that will bear the brunt of EU policies. Finally, the Department does not run the NHS; it is the professionals and management cadre of the NHS who should understand best the complex consequences of policies. What it does, therefore, is concentrate on developing a training function so that all areas of the Department can follow and deal with the EU and the UK's EU representation on their own. It reserves its own interventions for the more complex issues where there is more difficult formulating a view and coordinating within Whitehall. This strategy follows on the experience of departments that have been "European" for much longer, such as Environment, Food, and Rural Affairs, or Trade and Industry, and which found it unproductive to concentrate something as wide-ranging and important as EU relations in one area.

This means the Department is essentially facing two challenges. One is to "Europeanise" itself, a relatively insular Whitehall line department, by explaining to its various technical divisions and the NHS how they should follow, understand, react to, and shape EU policy. The other is to plug the Department into the various established mechanisms of UK representation, especially UKREP and the Cabinet Office so that it can most effectively use the UK's internal devices for formulating a "line" and then pursuing that line through all the various fora and decisionmaking bodies of the EU.

Northern Ireland, Scotland, and Wales

The devolved systems have a bigger problem, of course. A high degree of internal consistency within the Department of Health is likely because the Whitehall civil service uniformly answers to the UK government. Ensuring coherence in UK representation is by no means easy, but at least Cabinet government and civil service tradition make it possible to create a unified position. Ensuring coherence across the UK is harder for two reasons. First, the four governments might not agree, which might make forging a common view more difficult. Second, there is extra administrative complexity; unless a devolved government makes an effort to connect, probably via the Department of Health, with the UK's machinery of representation, and to develop its own information-gathering, it will be neither well informed nor able to shape EU decisions.

The devolved response has been two-pronged. On one hand, all three have Brussels offices most of them created in the 1990s to fly the flag, seek business opportunities and EU funds, and scan European horizons.¹⁰ Each has a full-time officer partially or mostly focused on health, able to gather information and make the case for their specific interests. These officials are integrated with both the rest of the staff in the regional offices, putting the

10. The UK is thought in the EU to be particularly good at this regional lobbying; Birmingham actually holds the laurels for opening the first of the regional offices. This means that the inherited cultures, though, tend to focus on the original reasons for those offices: the search for EU funds and inward investment. Their role in policy influence is usually much smaller.

emphasis on the Brussels aspect of their work rather than the connection with the health services. When there is an agreed UK position, regional offices can be useful extensions of that position; Scotland and Wales have different positions, networks, and reputations in the EU, and are able to lobby in fora that are closed to the DH as well as vice versa. On the other hand, they have made efforts to integrate their health departments with the DH. The DH and the devolved coordinators meet regularly, and there are virtual and face-to-face networks of communication about EU affairs throughout Whitehall which are shared with them.

The stability of this system can be doubted. Other member states might sometimes admire the coordination capacity of the UK and its ability to develop a shared line, a line that is then likely to be promoted with considerable professionalism. There is some evidence that the Department of Health in general, with its strong bias towards professional NHS managers and relatively small civil service cadre, is weaker than other UK departments in its ability and willingness to use these coordinating networks. There is also the fact that such networks, effective though they are, depend on political goodwill. But it depends on shared politics and shared political interests. Civil servants owe their loyalty to their government, after all. Political goodwill is best assured by having the same party in government around the UK. Labour's control of Whitehall, and its governments (with or without Liberal Democrats) in Cardiff Bay and Holyrood have allowed devolution to bed down, with politicians as generally willing to coordinate as their officials. The problem, though, is that someday Labour will lose a UK, Scottish, or Welsh election, and then the informality and reliance on goodwill of intergovernmental and European relations in health could be sorely tested. Like most of the UK's system of intergovernmental relations, the present situation in health can be handled with professionalism by the civil service only so long as all four capitals- Westminster, Stormont, Cardiff Bay and Holyrood- want to make the Labour party look good (Trench forthcoming).

Should the system lose its stability, and even if it does not, there is some evidence that the devolved systems are paying far less attention to the challenge of Europeanisation than the DH itself- and even the DH's effort was severely criticised by a few interviewees as inadequate to the challenges of responding quickly and effectively to Europeanisation. If the DH is acting on the conviction that what is required is the mainstreaming of EU affairs into overall health policy formulation, the devolved governments appear to be using, for all practical purposes, an older model of having a person who among other tasks coordinates European affairs, acting as the connection between the Brussels office, the DH networks, and the domestic policy system. There is reason to doubt that this level of effort is sustainable; one EU coordinator who also has other jobs, combined with one Brussels official, might be enough to track EU developments, but will not be able to draw on the resources of departments and health services in order to develop arguments and work out the consequences of policies. The staff could simply be overwhelmed and, given that devolved systems have no *necessary* representation anywhere in EU decision-making, there is a good case that they should make even more of an effort than states if they want to see problems and opportunities coming and try to respond.

The NHS

Finally, there is the NHS itself. What are the health services doing? There are three regions that have acted: Greater London, the West Midlands, and the Northwest. All three are working to identify major new policies and their consequences, and therefore act as funding finders as well as political antennae.

The London NHS has developed an interesting model of action on its own. London, thanks to some well-established activists, has a good record of developing networks across the city for various purposes, and these networks have been the basis for the London EU Business Sector Network. London is also seen by others as the region most preoccupied with patient and professional mobility due to, if nothing else, its transport links and perennial staffing problems. This Network is sustained largely by secondees, one from each of the five London Strategic Health Authorities and one representing the London Mental Health Development Centre. In Brussels, it piggybacks on London's European Office, which has a policy monitoring and briefing role and produces information according to an agreed work plan. Staff at London's European Office can also attend Brussels based events and give feedback to the London NHS. There is no dedicated staffer based in Brussels. Rather, a senior member of staff monitors EU policy developments that will impact on health, along with a number of other policy areas. Its important characteristic is its focus on the health systems engagement back in the region- in the policy work of the secondees and in their access to the London NHS at director level. Directors from each of the five sectors in London can then brief their respective Chief Executives before collective decisions are taken. That allows it to focus on the health services impact of EU policy and work it out in detail, in detailed communications to the NHS and lobbying in the EU.

Two other English regions also have NHS representation in Brussels. Like the Scottish and Welsh ventures, they are based in the organisations that generally work for the regions in Brussels, namely the offices run by Regional Development Agencies (RDAs). They are set up in Brussels for broader purposes of lobbying, information-gathering, and networking and have long focused on aid, spending programs such as research, and representation in the Brussels environment (which can bring extra benefits such as inward investment). The West Midlands and Northwest health programmes are both new, nearing their second year of work, and differ from the London model in that they employ a full-time, Brussels-based health specialist. If the London model puts the emphasis on NHS backup and information, the regional models focus more on intelligence and representation in Brussels. Theirs is a more traditional model of EU representation, one that has been very successful in other policy areas that want to benefit from EU activity and know about it in advance. The models are likely to spread and change as interest and resources expand and as funders try to use existing resources without duplication.

The drawback of all these schemes is, as one well-wisher of the London scheme observed, is that you can lead the horse to water but you can't make it drink. Even with the WTD bearing down on them, many managers paid little attention, or really awoke to it when they heard about it in the broader press, or found that they could not devise solutions. There is a limit to the ability of hospitals to move to shift work, and often a level of organisational

innovation is required that proved beyond the resources of NHS management in the little time they had left after they awoke to it. But despite this unpleasant shock, not one UK interviewee reported any coherent interest in EU scanning and intelligence from acute trusts, even if funding, benchmarking, and patient and professional mobility all matter to them. Instead, much of the interest has been from public health officials around the NHS who are curious about EU funding and policy opportunities.

These local NHS networks are also a useful resource for the Department of Health; the DH's international team can use them to identify people who can assist with the many demands for UK representation and participation in activities as divergent as accreditation and benchmarking assistance to new EU members. In the energy-, time- and information-poor environment of EU policymaking, even more than in most walks of life, there is influence and a role to be had merely in turning up and helping out. Furthermore, there is always, structurally, a problem with feeding information from the front line of anything up to high decisionmaking levels; the existence of networks that connect the NHS at director levels with the officials engaged in representing the UK in the EU gives the NHS a better sense of what is happening, and the UK officials a better sense of the potential problems and opportunities in policies.

Finally, it is at this level (and in the other functions of the devolved government offices at the EU) that EU funding can be won and used. London, for example, has a scheme in which successful EU bids for funding are flagged. The group then devises ways to expand them, making them pan-London, so that they can be resubmitted for more funds and a broader geographical remit.

CONCLUSION

Health systems of the EU are formally well shielded against European policy, obliged only to go along with the Commission's coordinating efforts, but they have a single, serious, vulnerability. They might be restricted areas of state sovereignty and solidarity, but they also are large organisations immersed in labour and product markets that they do not completely control. Those markets are the stuff of EU single market regulation, and they are shaped by a politics not of health but of the single market. Once the European Court of Justice had decided that health systems are economic activities like any others, and therefore subject to internal market legislation, the conditions under which health systems gain and use resources changed dramatically, regardless of formal state protection or the existence of ECJ principles that limit the ability of EU law to wholly upset health systems. The reason is simple enough; health systems are, like almost everything else in capitalist economies, adjacent to the markets in goods, services, and labour, and those markets are the constitutional and practical core of the organisation long known to ordinary citizens as "the Common Market."

The appropriate response, put abstractly, would be to focus on both the threats and the opportunities. The sense of threat is sometimes visceral – the irritation of policy experts, managers, and officials with somebody they see as less qualified who is treading on their turf. But there are good reasons to be worried, for example, about the enormous consequences that could come from the inclusion of health in the Services directive, and reason to lobby against it (as is indeed the UK health departments' line). The unpredictability of the ECJ – or rather its application of models of markets, rationing, and shift work that appear unrealistic to health analysts – should be a serious ongoing concern.

But all is not threat, a court and a bureaucracy gone mad. Sometimes the policy is reasonable even if the way it is coming about is unintended and undesired. Long hours, for example, would not be sustainable over time anyway, and we can see that their social and organisational underpinnings are seriously eroded. Younger doctors are less likely to see their profession as a quasi-religious vocation and more as something like a job (Harrison and Dixon 2000:47), which combines with the increasing proportion of female doctors who

demand a better work-life balance to put older, more macho, forms of medical education under pressure. In primary care, already, the 24-hour service of a personal GP is so badly eroded that Moon and North (2000:1-8) speak of practice-based rather than physician-based care. And it is relatively hard to argue *prima facie* that keeping doctors awake on very long shifts improves patient safety or anybody's morale. In this case, the impact of the EU (the WTD) could be seen as triggering overdue but beneficial debates about the structure of medical work and about the structure of acute care.

And sometimes there are opportunities. As regional office staff correctly note, there are many opportunities for EU funding of many kinds. Even when structural funds run out, there is room for collaborations in which a UK organisation joins a bid by providing a form of consultancy to health systems in poorer areas. There are also EU networks, which can lower the costs of interacting in international fora and which can create the personal connections through which ideas and information flow. And even if there is no verdict yet on the usefulness of the new mechanisms in health such as the High Level Working Group or the OMC (which have both scarcely started), at least some of them will matter, and all of them can be shaped right now.

Several of the interviewees for this work urged me to stress the opportunities, even as they spoke of using the WTD or the prospect of EU-wide benchmarking to 'scare' chief executives into paying attention. There are opportunities, but much of the story is of major challenges- of the political challenges of coping with the prospect of health regulated under the services directive, of the impact of ECJ decisions about waiting times and patient mobility, about the unknown consequences of policies as different as EU technology assessment and harmonisation of professional qualifications. The clearest opportunities are outside health services – in regional and research funding, or in public health where everything from cooperation on communicable diseases to work on tobacco control show the promise of work on the EU level. In health services, there is scope for learning from and benefiting over time from integration with the UK's 24 partners – but that will best happen, and the UK's health systems will play the game best, if they helped write the rules. And those rules are being written now.

APPENDIX:

THE EUROPEAN UNION INSTITUTIONS

The impact of the EU on health *services* stems from the substantial regulatory and policy powers that are part of its responsibilities for internal market. This reflects some basic points about the unusual structure of the European Union. The EU has four major relevant components: the Commission; the Council; the European Court of Justice; and the European Parliament. Each branch reflects very different interests and has very different powers. Briefly, they are as such:

- The Commission is the executive arm of the EU, charged with formulating and implementing policy. It has the unique right to propose legislation; there is no other source of EU legislation. It is divided into Directorates General, each with a permanent civil service head (the Director General) and a Commissioner. The Commissioners are the equivalent of ministers; each member state nominates one and the member states choose the President of the Commission, who then allocates the portfolios and presents the whole Commission to the European Parliament for ratification. While domestic politicians tend to say Commissioners should represent their country, and national characteristics are often clearly visible, in theory they represent, collectively, the EU. The DGs vary in age, status, and above all the treaty competencies and legislation they can enforce. Some, such as DG Internal Market, enforce powerful legal instruments (harmonisation of market rules) and have strong bases in the treaties and ECJ case law to propose more legislation; others, such as DG Health and Consumer Protection, have little power other than the power of suggestion and budgets with which to create European networks. They are like ministries anywhere, but perhaps more competitive, jealously guarding their autonomy, sneaking into each others' territory, and competing for "new" policy areas and tools they can occupy.
- The Council is the key decisionmaking body in the EU. It is where the member states have their votes on EU legislation, and no EU legislation has force without the Council vote. Each Treaty revision, and the proposed constitution, changes the voting rules, so

that some areas are subject to qualified majority voting (QMV)(including many internal market areas) and others require unanimity. Over time, and with expansion, more areas have become subject to QMV. There is a Council for heads of state, and sectoral councils which have met regularly for some time (including a Health Council, which has gained in importance). Civil servants in COREPER (council of permanent representatives) do much of the preparatory work and try to reach decisions. It is convened by a Presidency, which does much to set the agenda. The UK will have a Presidency in 2005; this means, for example, that opponents of the inclusion of health in the proposed Services Directive want the issue resolved before the UK presidency because they do not want the UK constrained by the need to appear even handed when in the chair.

- The European Parliament is the most democratic, least important, and most complicated part of the structure. It is elected across the EU and the parties, at least in the chamber, sit by party groups rather than nations; the result is sometimes uncomfortable (the UK Conservatives sit in the very pro-European, explicitly federalist, Christian Democratic grouping called the European People's Party). It is, unfortunately, a "second-order" body, with citizens typically voting in the European elections to express discontent with incumbent member state governments rather than on the basis of their opinions about EU politics and policy (Hough and Jeffery 2003). The EP cannot propose legislation; rather, it can, under a variety of fiendishly complex voting systems, hold hearings and vote on proposals. Depending on the voting system at work in a given policy area (i.e. the treaty components that justify the legislation), the EP can heckle, slow, modify, or block legislation. It is also an excellent way to publicise issues and put pressure on member states and the Commission, and a comparatively accessible forum for those who cannot lobby via a member state.
- The European Court of Justice is, seen historically, the surprising part of the whole EU structure. It was originally created as a minor body to be charged with keeping the different branches of the organisations that became the EU in equilibrium. However, early on it determined that it also had jurisdiction over member state policies that it deemed to be in violation of the Treaties or EU legislation. The result has been the development of an enormous body of EU jurisprudence, and ECJ decisions that radically expanded the scope of EU law. Given that freedoms related to commerce are at the core of the EU, they are the most likely principles involved in ECJ expansions of EU powers, which gives many of its decisions an apparent liberal tinge. At times this comes from the Court directly interpreting the Treaties, and is very difficult to overturn with legislation (as in the patient mobility cases). Other times, when it is interpreting legislation, the problems created can be resolved by more legislation, as in the issue of on-call time under the Working Time Directive. The Court takes cases referred to it, such as the *Watts* case, which means that (sometimes quite low-level) courts across Europe can win fame and importance by referring major issues upwards to it. Cases are thought out by advocate-generals, whom the justices tend to follow in their decisions.
- There are other bodies, intended to represent various interests or serve watchdog functions. Two are legislative, advisory bodies. The Economic and Social Committee (ECOSOC) convenes representatives of employers and unions to comment on some

legislation. It is moribund. The Committee of the Regions (CoR) is less clearly defunct; it represents regional and local governments from around the EU. It is purely advisory; like ECOSOC it must be consulted on some issues but need not be listened to. It was created as part of the Maastricht treaty as one of a number of devices inserted at the behest of powerful German and Belgian federal states that were alarmed at the competencies they were losing to the EU. A cacophony of politicians ranging from Greek mayors to the presidents of regions with tens of millions of people, it still gets some attention from leading regional politicians but has disappointed most observers.

REFERENCES AND FURTHER READING

While the recency and speed of developments in EU health mean there is not much other literature to read yet, there are a number of books and articles that are useful, and far more thorough, introductions to the issues here. Randall (2001) is a clearly written, only slightly dated tour of all the major issues, sensitive to the politics and policy. The work of the European Health Observatory is immensely useful; their two key books on the topic to date are Mossialos and McKee (2002) and McKee, Mossialos, and Baeten (2002), and, for enlargement, McKee, MacLehose, and Nolte (2004). Tamara Hervey is the leading legal specialist on the issue, and Hervey (2002) is still the best short introduction to the legal issues. The journal *Eurohealth*, associated with the Observatory, is a useful way to keep up to date with issues as they arise, and it is worth subscribing to the electronic newsletters produced by, for example, the London EU Business Sector network or its equivalents. For a general introduction to EU politics and policy, Nugent (2002). Borrás and Jacobsson (2004) provide a judicious academic analysis of the Open Method of Coordination; see also the OMC website maintained by the University of Wisconsin, at <http://eucenter.wisc.edu/index.htm>. The best discussion of the relationship between the UK's devolved systems and the EU, although without a special health focus, is Bulmer *et al.* (2002), particularly its conclusions, and will be joined by the concise and very helpful Jeffery (2005 (forthcoming)), of Edinburgh University; this is available from the author or the Constitution Unit, University College London. The EU website, www.europa.eu.int, contains every official EU document cited and many more.

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