

CONCLUSION

Health Technology Assessment and Health Care in the European Union

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Abstract

The papers on the 16 European countries presented in this issue show their great diversity of health systems. Health technology assessment (HTA) has been institutionalized in a number of members of the European Union and has a growing impact on health policy. A remaining challenge is to see HTA visible and useful at the European level, which requires more active coordination of national and regional activities. A network of HTA programs and researchers has been established. The HTA-Europe Steering Committee has suggested a number of actions by the European Commission to promote further coordination. The most important conclusion of the HTA-Europe report is that a permanent coordinating structure is needed at the European level.

Keywords: Technology assessment, biomedical, European Union, organization and administration

The country papers in this issue are very rich in detail and insights concerning health care in the European Union. Only a few of these will be summarized here.

The first and most important general observation is that the population of the 16 countries described enjoys essentially universal access to healthcare services. Some countries (the United Kingdom, Sweden, Denmark, Finland, Spain, and Italy) cover any individual living in the country. Other countries manage, through a mix of public and private funding and services, to cover close to 100% of the population.

The second observation is the complexity and diversity of the healthcare systems of the countries described. For the outsider, European healthcare systems are sometimes described as if they are quite similar in their organization and financing. Nothing could be further from the truth. Each country has a healthcare system that has evolved over time, with decisions based on social and cultural preferences. While trends such as population aging and increases in healthcare expenditures are common, mechanisms for dealing with these issues generally are not. Diversity may be a strength. The countries of the European Union present a series of natural experiments. They have much to learn from each other in the study of the strengths and weaknesses of other healthcare systems (including the development and use of HTA).

The healthcare systems of the 16 countries are all continuing to evolve, in a process that has come to be called "healthcare reform" (12). Healthcare reform often includes paying attention to the value for money of the healthcare system and attempts to make health care more efficient or more evidence-based. Reforming health care may mean changing the financial incentives or management structures in a particular healthcare system. It may mean new programs for dealing with an aging population. It may mean new regulations or other attempts to control or rationalize health technology.

Finally, an impetus for change in many countries is population dissatisfaction with the healthcare system. For example, the Italian paper in the report states that a study showed that the Italian healthcare system was "the least popular health care system in Europe in 1990." Blendon et al. (3) has compared the levels of satisfaction to the levels of healthcare spending per capita. If Sweden is excluded from the analysis, public satisfaction in Europe is associated with higher levels of spending. The Netherlands, Germany, and France demonstrate higher levels of public satisfaction and spend more than Great Britain. A 1997 study reported similar findings, although Denmark and Finland were found to have high levels of satisfaction despite relatively low levels of spending (10). Blendon hypothesizes that higher satisfaction is related to increased availability of more sophisticated healthcare technologies, more choice of physicians, less waiting and travel time, and the age and modernity of healthcare facilities. Hurst (8) has suggested that countries with reimbursement or contract models of care with fee for service have higher levels of satisfaction. Presumably, this is because such models may result in more responsiveness to consumer wishes. What does seem clear is that citizens in a number of countries are demanding a more patient-oriented approach to the delivery of health care (12).

In the countries of the European Union, national HTA programs have been established during the last decade or so (Table 1). Leaders include Sweden and Denmark, which began to assess health technologies in the early 1970s, and the Spanish province of Catalonia, which established a Committee on Health Technology in 1984. Countries that have established or designated national programs to become involved in healthcare technology assessment include Sweden (1987), France (1990), the United Kingdom (1990), Spain (1994), Finland (1995), and Denmark (1997). In addition, regional or provincial programs have been established, especially in Spain and Italy. In Spain, regional programs are found in Catalonia, the Basque Country, and Andalusia. Some countries, such as the Netherlands and Switzerland, have extensive HTA activities. Finally, interest is growing in a number of other European Union countries, including Italy, Germany, and Greece, and in eastern European countries, including Poland, Hungary, Czech Republic, Romania, and Lithuania.

HTA is organized and implemented in a somewhat different manner in each country. One of the main determinants of such differences is the nature of the health system of the country. Some countries, such as Sweden, Spain (and several provinces, including Catalonia), and France, have an actual public agency for assessment of health technology. Others, such as the Netherlands and Switzerland, implement HTA primarily in relation to payment for health care through sickness funds and insurance companies. The United Kingdom has embedded HTA in the R&D Programmes of the National Health Service (NHS) and the Department of Health in an attempt to bring HTA into all administrative and clinical decisions. Likewise, methods differ, although countries are showing a tendency to converge in their use of methods. Sweden and France focus on synthesis of existing knowledge as their most important tool. The United Kingdom and the Netherlands also put more emphasis on commissioning prospective studies on high priority subjects.

These papers illustrate that technology assessment has begun to become an important part of health policy making in many countries. A number of interesting initiatives concerning the use of HTA have been taken in these countries. Some examples include a physician network in France, extensive attention to implementation of HTA in Spain (and Catalonia),

Table 1. Overview of Health Technology Assessment Activities in 16 European Countries

Country	HTA activities
Austria	Small HTA activity in the National Academy of Sciences; some studies and analyses.
Belgium	Some studies and analyses; little impact on policy.
Denmark	National program established in 1997; studies and analyses for more than 10 years, sometimes with considerable policy impact.
Finland	Long history of interest in HTA; assessment agency FinOHTA established in 1995.
France	National agency (ANDEM) established in 1989; name changed to reflect broadened mandate in 1997 (ANAES); increasing use of coverage as a policy to manage health technology; formation of a new agency in late 1997 to expand HTA activities in France; growing attention to cost-effectiveness.
Germany	Substantial and growing interest in HTA; active discussions on how to institutionalize HTA; considerable interest and support from the Federal Ministry of Health, which is funding HTA reports.
Greece	Some studies and analyses; law in 1997 established a national HTA agency, being implemented.
Ireland	Some studies and analyses; growing interest; plans to establish a national committee for HTA.
Italy	Growing number of studies and analyses; growing policy impact; Institutionalization weak, both nationally and regionally.
Luxembourg	Little activity, although interest may be growing.
Netherlands	Long history of interest in HTA; national fund for HTA established in 1988; policy studies done by Dutch Health Council and others; many policy papers by government and advisory organizations; growing use of HTA in coverage decisions; active research field; national coordination mechanism for HTA being established.
Portugal	Some studies and analyses; growing interest; discussions of establishing a national HTA agency.
Spain	Advisory Board on High Technology established in 1984 in Catalonia; evolution leading to the Catalan Agency for Health Technology Assessment in 1994; Basque Country Office for Health Technology Assessment established in 1992; the National Spanish Agency for Health Technology Assessment established in 1994; the Andalusian Agency for Health Technology Assessment established in 1996.
Sweden	Substantial activity at all levels; national agency (SBU) established in 1987; continual expansion of mandate and budget of SBU to encompass all aspects of health care; growing impact on policy.
Switzerland	Active and explicit coverage policy based on HTA; many policy options under coverage; substantial research activity; national coordination mechanism for HTA activities being established.
United Kingdom	Substantial activity at all levels; national program within the Department of Health R&D Programme; large and growing investment in HTA; great attention to priority setting and to dissemination of results; several important institutions, including the National Coordinating Centre for Health Technology Assessment and the first of an international network of Cochrane Centres.

development of special ambassadors for disseminating HTA in Sweden, and an Information Systems Strategy in the United Kingdom.

The field of health technology assessment has illustrated that it can identify technologies and produce assessments in a timely fashion. Technology assessment agencies have successfully involved leading physicians, administrators, and other healthcare professionals in their work, but problems remain. Key problems, for example, are that clinical providers

have been little influenced by assessment and that assessors have not yet learned to reach out to the general public.

A TENTATIVE EVALUATION OF HTA ACTIVITIES IN EUROPE

The steering committee for the HTA-Europe project suggested that it would be useful to make a tentative evaluation of HTA activities in Europe, based on the country papers and on committee members' knowledge.

The evaluation will be presented in the following categories:

- Functions of HTA;
- Focus of HTA;
- Type of technology;
- Type of healthcare provider; and
- Level of the system.

Functions of HTA

Use of HTA seems to be increasing in all countries in the European Union. The common use of such terms as "evidence-based medicine" indicates an orientation to use HTA results and similar information as a guide to policy and practice.

In countries that have developed HTA systems, use at the policy level is generally good, although more remains to be done. Use of HTA at the management level (hospitals, for example) seems to be limited in most countries, however, and it is widely acknowledged that clinicians have not actually changed their practice to agree with HTA results despite the rhetoric about evidence.

Doing HTA likewise has increased dramatically in a number of countries, notably the United Kingdom, Sweden, Spain, France, and the Netherlands. In other countries, HTA seems to be done more frequently than in the past. However, the volume of HTA is quite insufficient to answer the thousands of questions and to assess the thousands of technologies that need assessment.

Funding and supporting HTA is likewise growing in a number of countries. Dramatic rises in expenditures have especially been seen in the United Kingdom and the Netherlands, where the emphasis is more often on prospective research.

Steering or coordinating HTA has changed dramatically during the past few years, with the development of formal national and regional programs. Countries that have made obvious progress in this area include the United Kingdom, Spain, and Sweden. On the other hand, the Netherlands is one of the most active supporters of HTA in Europe, but it is only beginning to develop a basic system or coordinating structure for HTA. Switzerland also has had no coordinated HTA system despite considerable activity, but it too is in the process of establishing national coordination activities.

Supporting/promoting HTA at the policy level has likewise been seen in a number of countries. HTA does not become accepted for theoretical reasons; it is accepted because of success. As agencies and programs have carried out useful assessments, active support for HTA has grown. A good example is the strong support from the Dutch Parliament for HTA activities in the Netherlands.

Focus of HTA

It has often been said that the healthcare system is actually a "disease care system" with little activity related to health. The same could be said of HTA. The general focus of HTA until recently was on expensive, new diagnostic or therapeutic procedures, usually with expensive equipment involved. There have gradually been changes, however. In 1986 a

Canadian document advocated needs-based HTA, that is, starting from the health condition instead of the technology (6). This approach has become more common and is especially prominent in the United Kingdom and Sweden. For example, the Swedish Council on Technology Assessment in Health Care (SBU) has carried out assessment in such areas as back pain, diabetic retinopathy, mild hypertension, and stroke. In the United Kingdom, assessments often concern systems of care for people with certain problems, such as diabetes or mental illness. In the Netherlands, too, systems of care for mentally ill people are a focus.

The field of prevention by screening has been comprehensively assessed, especially by the U.S. Prevention Task Force (14), which has stimulated increasing interest in Europe as well. In the HTA-Europe project, partners examined several preventive technologies in their respective countries, showing that prevention and screening procedures often seem to be prematurely adopted without adequate assessment.

In an era of chronic diseases, rehabilitation and supports for the disabled should become of greater concern. Technology has much to offer disabled people, but it must be assessed just as in any other area. Few such assessments have been done. Still, this too is changing. For example, the Rathenau Institute, an advisory body to the Dutch Parliament, has funded studies of technology for disabled people (11). SBU, the Swedish HTA agency, has carried out several studies related to rehabilitation.

Despite the obvious importance of old technology, indicated in statements about the lack of assessment in this area, programs still focus largely on the new technology. However, this too seems to be changing. The Cochrane Collaboration has undertaken to identify and review randomized controlled clinical trials in many areas of existing practice. In the Netherlands, an extensive Delphi-like process produced a list of 126 technologies that were in common use but still needed assessment; the list was later updated to 194 candidate technologies. Assessment is under way in a number of these cases.

HTA can deal with an individual technology, a group of related technologies, or a service or program for certain problems. The majority of assessments probably present information on one or only a few technologies, although assessments of systems are becoming more prominent.

Finally, HTA leads to recommended actions. Such actions have often involved regulation, and changes in payment are currently a popular option. Educational strategies are not so often proposed. Because of the limitations of formal policies, however, HTA agencies and others have attempted to develop new strategies for dissemination and implementation of HTA results (7).

Type of Technology

The most assessed type of technology surely must be pharmaceuticals. Pharmaceuticals have been subject to systematic assessment for safety and efficacy for decades. A great deal of assessment information on drugs is available. On the other hand, the European system of pharmaceutical regulation does not deal with a number of important questions, such as cost-effectiveness, relative efficacy, and appropriate indications. HTA agencies are being increasingly called upon to fill such gaps. In France, a new program has been established to assure comprehensive assessment of pharmaceuticals.

Medical equipment is subject to a reasonable amount of assessment, but this assessment is mainly technical, and generally does not even deal with clinical efficacy. HTA agencies have often been involved in assessing equipment and procedures that involve equipment.

The diagnostic and therapeutic procedures of healthcare practice have been a main emphasis of HTA since its earliest beginnings. While this is appropriate and will continue, other priorities are emerging.

A field that has great potential as well as great potential costs is telematics, the application of computers and communications in health care. There are literally thousands

of applications of telematics possible in health care. Knowledge of the benefits and costs of telematics is only beginning to be developed. While activities have begun, the task is enormous.

Type of Healthcare Provider

As stated above, the main emphasis of HTA from its beginnings has been on expensive diagnostic and therapeutic procedures. This means that the main providers involved in HTA have been specialty physicians. They have been researchers in the field, subjects of the research, and objects of attempts to change their behavior. Gradually, however, primary care and general practice have become the subject of HTA research. The Netherlands is a leader in this field.

Nurses have not been very much involved in HTA. Likewise, in dentistry, HTA has had almost no involvement or impact. Assessment is difficult in these areas because of a paucity of well-designed research studies on efficacy and safety. As mentioned already, in some other types of services, such as physiotherapy, assessment is beginning. The problem in many such areas, as with dentistry and nursing, is the relative lack of prospective research.

Level of the System

Consumers. Traditionally, the role of consumers in health care, including research and health technology assessment, has been limited. It has been recognized that this situation needs to change. The choice of a particular technology depends heavily on the interaction of the patient and the physician. Patients tend to equate quality of care with the ordering of tests or the prescription of treatment, although they are also very concerned with quality of life, while physicians sometimes emphasize more “medical concerns,” such as morbidity and mortality (2). This implies that it is of the utmost importance to involve consumers in discussions concerning healthcare technology.

When identifying technologies in need of assessment, consumers’ experiences could be of great value. In data collection and testing, consumers are often involved as subjects. With their perspectives, consumers might have a valuable input to research design. Synthesis activities might be improved by consumer input. And perhaps the most important consumer role could be in dissemination and implementation of HTA results. Educated consumers can react to ineffective care or cost-ineffective care, especially by demanding beneficial care. But obviously, they must have good information as a basis for such demands.

Consumers need to become partners in the HTA process. There are considerations along these lines in such countries as Sweden, the Netherlands, and the United Kingdom, but developments in general are still at an early stage. The United Kingdom is perhaps the furthest along. The precursor of the Cochrane Collaboration, the National Perinatal Epidemiology Unit, produced a massive work, *Effective Care in Pregnancy and Childbirth*, which involved consumers deeply in HTA in this area (4). Subsequently, consumers have been involved deeply in the Cochrane Collaboration. The NHS R&D Programme has also involved consumers in all key decision-making structures (5).

Clinical Professionals. The primary responsibility of medical professionals is to provide high-quality health care to their patients. To meet this responsibility requires continual self-monitoring and improvements in care. Improving quality means applying existing and new knowledge and technologies in an appropriate manner. This has been called “evidence-based medicine.”

Medical professionals and others have been active during recent years in producing clinical guidelines for this purpose. A concern related to HTA is that guidelines are generally not based on a structured review of all available scientific literature, since carrying out a structured review is time-consuming and expensive. The problem with guidelines underlines

the importance of expanding synthesis activities and in cooperating in international efforts related to HTA and synthesis. Cooperation among such movements as evidence-based medicine, the Cochrane Collaboration, and HTA is becoming more and more of a priority.

Education for medical professionals is also a critical concern. In the European Union there is a "principal agreement" that all member states recognize the certificate or diploma of medical professionals. This does not mean that medical education is the same in all member states, but it must meet minimum standards. It could be beneficial if all member states included HTA and evidence-based medicine in their education for medical professionals.

Hospitals (Especially Teaching Hospitals). Users of HTA are diverse. Hospitals are an important potential user, since they are the main purchasers of equipment and they provide the bulk of expensive, high-technology services. HTA can be used by hospitals for guiding difficult choices, especially in balancing organizational and community needs (9). Hospitals are often involved in the implementation of HTA information. However, they have a major problem in finding reliable information, since most information comes from industry. Synthesis reports could be designed to support policy making at the hospital level.

HTA Agencies and Other Providers of HTA Information. Such organizations function to provide information. But without a system for HTA, they may not be effective. A complete system for HTA would monitor technological change at all stages of technological development and diffusion.

A system for HTA could be said to have five main tasks:

1. Identification: monitoring technologies, setting priorities;
2. Testing: data collection and analysis;
3. Synthesis: collecting and interpreting existing information;
4. Dissemination: providing HTA information to users; and
5. Implementation: helping to assure the application of HTA results.

These five tasks can be divided among several different agencies or programs. However, coordination of the tasks then becomes quite important. Furthermore, methods should be matched to the problem being addressed. The EUR-ASSESS project is an example of a project working to assure a degree of standardization of methods involved in HTA (1).

A core task in HTA is synthesis. A synthesis should actually precede the collection of data (how can one know what data are needed if one does not know what studies have already been done?). But this is seldom the case. Synthesis can also often lead to a judgment of the usefulness of a particular technology. Still, despite rapid developments in the area of synthesis, led by the Cochrane Collaboration, synthesis is not a method in widespread use in most European countries. Synthesis needs more emphasis. Methodologic developments are also still necessary.

It is also known that the results of HTA have not been effectively disseminated throughout the world. Effective dissemination requires contacting the potential users and convincing them of the importance and validity of the information. Use of the Internet and the World Wide Web is increasing. Direct educational activities, especially for clinical providers, are also necessary.

Industry. The industries involved in HTA are mainly the pharmaceutical industry and the medical devices industry. Industry has much to teach the rest of the healthcare system, since all drugs are assessed before they come into widespread use. Ideally, all technologies would be tested before they came into use. As pointed out earlier, however, the assessments carried out in the pharmaceutical area are actually quite limited, and access to information is also a problem.

Industry sees the present economic climate of the Europe Union as difficult, especially for pharmaceuticals. This situation will probably only become more restrictive. Governments are demanding more HTA information to rationalize the use of drugs and, in some cases, medical equipment. (For example, France has a new agency to evaluate medical equipment, including its cost-effectiveness.) To survive in such a demanding environment, industry needs to begin HTA early in the research and development phase of a technology. Many companies have already realized this fact and are acting. The rapidly growing field of pharmacoeconomics is one manifestation of this realization.

A major problem is that developments from industry are often not related to health needs but are technologically driven. Industry could work more effectively with others, including those in HTA, to base developments on information such as burden of disease. Significant elements of the industry have already begun such activities.

National/Regional Government. Governments in a number of European Union countries have taken the lead in encouraging HTA through a number of actions.

A strategy for HTA as part of research policy has been developed in a number of countries. Catalonia is an interesting example. HTA needs to be approached as a bridge between clinical research and policy making. This means that scientific excellence must be coupled to societal relevance.

In some countries, a large number of organizations are involved in HTA. These organizations may or may not network toward a common goal. Cooperation within and between such organizations is needed to avoid duplication of work and to stimulate the sharing of results. The United Kingdom has grappled with this problem with some success. The Netherlands has not yet effectively addressed the problem.

Other interesting policies that can be linked to HTA include:

- *Coverage.* While coverage of health services differs from country to country, all countries need a structure to assure use of HTA in coverage decisions, even if they do have a health service instead of an insurance system. An interesting example is the use of HTA to guide coverage decisions in Switzerland. The Netherlands and Spain are countries actively working to improve their coverage decisions, and France is putting more emphasis on this area as well. Such countries as Germany, Belgium, and Austria have made few attempts in this direction as yet.
- *Planning and regulation.* Regulation, especially regulation of numbers and placement of services, has an important role to play in assuring appropriate access without excessive services. National and regional regulation can be based on HTA to a greater extent than they are. The Netherlands is an example of a country that carried out effective HTA linked to such decisions.
- *Guidelines.* Most countries of the European Union are actively involved in setting standards or criteria for quality of care, including the development of guidelines. Many groups develop clinical guidelines. However, implementing guidelines into clinical practice is not yet effective, in part because physicians and other professionals are not familiar with the process of developing, disseminating, and implementing high-quality guidelines. Effective dissemination requires active participation of professionals. National organizations of physicians and other professionals can take a leadership role in this area.
- *Educational policy.* It would be desirable to have HTA as part of the education of all healthcare professionals. Special courses for policy makers, manufacturers, insurers, and so forth could also be beneficial. Longer educational and training experiences are needed for those who will work in HTA.

COORDINATION OF HTA AT THE EUROPEAN LEVEL

The European Commission could carry out a number of actions to stimulate and encourage HTA:

- *Collecting, collating and disseminating information on emerging technology issues.* The field of “early warning” or early identification and assessment of important technologies is being institutionalized in several countries as part of the activities of HTA agencies and programs. A network of such activities is being formed. *The European Commission could assist in the support of this network.*
- *Collecting and disseminating information on priorities in HTA.* HTA is a form of policy analysis, which implies that policy makers must have a strong input to determine the priorities for research and research questions. This poses a common problem for all countries. *A mechanism for sharing information on priorities developed in different countries could be of benefit to their own programs.*
- *Collecting, collating, and disseminating information on emerging plans and programs for HTA.* HTA activities are evolving rapidly in many member states of the European Union. Each country or region tends to carry out its own activities without taking advantage of the lessons that could be gained from others. *The European Commission could assist in developing mechanisms for sharing such information.*
- *Ensuring that the findings of HTA from across the world are readily available across the European Union.* The volume of information from HTA studies is increasing at a rapid rate. Results of HTA are of increasing common interest to both doers and users of HTA in different countries. *The volume of HTA work points to the need for more effective information sharing, including clearinghouses and information links, at the European level.*
- *Organizing possibilities for joint assessments and supporting joint assessments agreed on, when priorities are similar among member states.* There have already been significant duplications of effort among European HTA programs, while many other technologies remain unassessed. Expertise in one country is not effectively utilized for the benefit of those in other countries. *The European Commission could help develop mechanisms for coordinating assessment work among member states.*
- *Providing opportunities for developing, defining, and sharing best practice in undertaking and reporting assessments* (13). The methods for assessment are relatively undeveloped, and few mechanisms exist to take action based on the results of such evaluations. *The European Commission could fund methodologic development. An area needing stimulation is social, ethical, and legal analysis.*
- *Providing opportunities to analyze and discuss methods of connecting HTA more closely to health policy and practice.* Within the diverse health systems of the countries of the European Union, there are many lessons to be learned concerning methods of influencing the development, adoption, and use of health technology. *The European Commission could assist member states to come together to learn from each other’s experiences in this area.*
- *Organizing and funding training for assessors and decision makers in the European Union in assessment methods, particularly (but not exclusively) for countries with relatively undeveloped HTA activities.* More and more researchers and clinicians are becoming interested and involved in HTA, and as a consequence agencies are under constant pressure to provide information to policy makers and to provide training and education for researchers as well as for users of HTA studies. *There is a need for a European approach to education for HTA. One possibility would be to have a network of institutions. An inventory of such institutions is a high priority.*
- *Supporting those seeking to develop HTA in European Union countries that are not actively involved in HTA.* As demonstrated in this report, only a relatively small minority of the countries of Europe (including future members of the European Union) is deeply involved in HTA. *The European Commission could support educational and consultative activities aimed at helping to institutionalize HTA throughout Europe.*
- *Organizing cooperative periodic meetings of partners to discuss all of these issues. Support is needed from the European Commission for such opportunities to come together.*
- *Designing and organizing a system for coordination and cooperation.* In sum, the activities described here are quite complex. There is a need for designing a system of coordination acceptable to all member states. *The European Commission could give support to such system design and integration.*

European Coordination

The HTA-Europe project, as well as the EUR-ASSESS project, was aimed at improving coordination of HTA activities in the European Union. The main conclusion of this report is that it would be beneficial for the healthcare system of European Union countries for the European Commission to assist the establishment of a coordinating mechanism for HTA at the European level. *It should be quite clear that what is being proposed is not a new European agency.*

There are four interdependent needs for an effective mechanism:

1. A board or steering body representing all member states, in addition to a smaller executive committee or board for continual oversight.
2. An administrative center to support all activities of the network.
3. A mechanism to assure full use of the relevant expertise and commitment of different programs and individuals in the European Union. In summary, this would mean a system in which important substantive functions are decentralized to different sites in European Union countries.
4. Funding to cover the added activities inherent in a European program of work.

The principle is to utilize and help strengthen the existing network under the principle of subsidiarity. The main recommendation of this report is that the European Commission assist in the establishment of such a coordinating mechanism.

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