



# A HEALTHY MARKET?

## Health Technology Assessment in Context



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 STOCKHOLM NETWORK

# Stockholm Network Papers on Health Technology Assessment

## Health Technology Assessment in Context – Paper No. 2 - July 2007

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This paper considers the development of health technology assessment (HTA) within its broader economic, political and historical context.

Whilst the introduction of HTA across OECD countries has been widespread there is considerable variation in how and to what effect it is employed. The historical development and evolution of healthcare systems in post-war industrialised countries has created differing organisational and institutional frameworks in which HTA regimes operate. As cross national study of the political history of medical technology will show, the arrangements that link technological innovations and healthcare delivery account for the persistence of cross national differences in how decisions are made, how evidence is used, how HTA is conducted and how HTA is implemented.

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As discussed in the Stockholm Network's introductory review<sup>1</sup>, HTAs were conceived as a response to the growing complexity of healthcare-related technologies. They allow key decision-makers (legislators and civil servants but also local policymakers, clinicians, insurers and physicians), to make decisions about the value of additional health benefits by providing them with a tool to appraise healthcare-related technologies on the basis of high quality and trusted evidence.

Decision-makers faced with the need to assess the value of healthcare-related technologies, are motivated by differing - and sometimes competing - health policy objectives. The desire to provide people with the best health care and to have an equitable distribution of care – that is to say, to have a homogenous and reduced morbidity and mortality rate among a given population - is tempered by the need to control and contain national expenditure on health and to allocate healthcare-related resources efficiently.

The difficulty for policymakers is to find and appraise methods for the evaluation of health interventions according to these objectives, to understand their complexity and, above all, to prioritise them. OECD countries have invested in HTA as a means to gather high quality, trusted information to assist healthcare decision-makers faced with this challenge.

### **How did it all start?**

Advances in health technology typically bring with them social and political dilemmas, particularly where matters of life and death are affected by human judgments and choice. Contraceptives, organ transplantation and more recently gene-therapy provide examples where in the last three decades healthcare-related technologies have challenged societal norms surrounding perceptions of human life and death.

Technology assessments (TA) arose in the 1960s as a response to the innovative leap that post-war industrialised countries faced and the need to regulate the unintended, (and at times negative) consequences of new technologies. In 1967, Emilio Daddario, introduced the term in the House of Representatives as the means to provide a balanced appraisal to policymakers, stating;

“Technical information needed by policymakers is frequently not available, or not in the right form. A policymaker cannot judge the merits or consequences of a technological program within a strictly technical context”.<sup>2</sup>

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<sup>1</sup> Pugatch and Ficai, Introduction to Health Technology Assessment, 2007

<sup>2</sup> Cited in Goodman HTA 101, Introduction to Health Technology Assessment, 2004 p. 10

The recognition that a policy tool was required to assess the impact of technologies led to the creation of the Office of Technological Assessment which became operational in 1974.

Although medical technologies have been subject to evaluation for at least two hundred years, HTA, in its current form, only became widely employed in the post-industrial period. Major innovations in medical care resulted in positive social, health and economic impacts that had to be weighed against their, sometimes negative, ethical, legal and political implications, as well as assessed in terms of clinical performance, cost-effectiveness, safety and ease of operation.<sup>3</sup>

The expansion of HTA reflects the worldwide concern surrounding healthcare regimes as the rapid development of new and expensive technologies has increased the cost of providing health care whilst achieving, in some cases, ever more marginal health benefits. The increased expenditure on health in general and the rising costs of new medical technologies in particular has led policymakers in developed countries to question whether the benefits of medical technology are worth the costs.<sup>4</sup> For this reason decisions concerning healthcare-related technologies have become increasingly focused on cost and efficiency since the 1970s.

### **Evolution of National HTA Bodies**

This section provides a brief review of different national HTA bodies. Although this paper does not deal with the nuts and bolts of the evaluation process of these bodies (such analysis will be provided in the third paper in the series), it nevertheless reveals how the wide range of organisational arrangements used by OECD nations to finance and deliver healthcare result in a variety of rates of diffusion and levels of uptake of healthcare-related technologies.

### **Europe**

A shift towards the extension of the universal provision of health care has occurred throughout Europe. Universal rights exist in Denmark, Greece, Ireland, Italy, Portugal and the UK, whilst very near universal rights exist in Belgium, France, Luxembourg and Spain.<sup>5</sup>

The nature of nationalised health services in Europe has meant that most countries in Europe have established HTA programmes linked to and supported by the national government which have a large amount of influence on the adoption and distribution of healthcare-related technologies.<sup>6</sup>

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<sup>3</sup> Goodman 2004 p. 28

<sup>4</sup> Elhauge, *The Limited Regulatory Potential of Medical Technology Assessment* Virginia Law Review, Vol. 82, No. 8 Symposium on Regulating Medical Innovation 1996, p. 1533

<sup>5</sup> Abel-Smith and Mossialos Occasional Paper in Health Policy No. 2 *Cost Containment and Health Care Reform: A Study of the European Union* London School of Economics and Political Science 1994 p 10

<sup>6</sup> Perry and Thamer Evaluation of Health care Technologies in the United States Compared to Canada and European Countries Journal of Public Health Policy, 1999, Vol 20, No. 2, pp. 168-191

However, differences occur in the level of interest countries take in HTA, and in their approach to it. These differences are mainly based on the degree of government control over health spending and the degree to which healthcare financing and delivery systems are publicly controlled.<sup>7</sup>

States fall into three major groups: those financed by a mixture of social and private insurance with mainly private providers i.e. the Netherlands, those financed mainly by social insurance with mixed public and private providers such as France and Germany and those financed mainly by taxation with mainly public providers such as the UK and Denmark.<sup>8</sup>

## **United Kingdom**

The Beveridge report of 1942 paved the way for the UK to develop a welfare state model which included a health service with the primary goal of universal healthcare provision. As a result, the National Health Service (NHS) was created after the Second World War, under the National Health Service Act. It is a single payer, directly administered health system, funded by taxation, with mainly public providers.<sup>9</sup>

The central government determines the capital and current budgets of regional health authorities and applies cash limits to the budgets of health authorities. It also controls expenditure on drugs by determining the budgets given to each general practitioner.<sup>10</sup> The government's monopoly over the uptake and diffusion of healthcare-related technologies allows it to ration medicine and treatments directly, either by price, by omission or by long waiting lists, which have tended to characterise publicly funded health systems. In addition, HTA allows a form of rationing by delay, for example by ensuring that expensive new technologies are first provided in hospitals which have the capacity to evaluate them. In addition placing cash limits on hospital budgets encourages health authorities to rationalise their stock.<sup>11</sup>

HTA programs are linked to and supported by the national government. The NHS Research & Development Health Technology Assessment Programme, for example, is a national programme established and funded by the Department of Health with the purpose of ensuring high quality research on the costs, effectiveness and broader impact of health technologies.<sup>12</sup> There are other HTA bodies, directly or indirectly linked to the NHS, whose areas of work include regulation, standards, public welfare and central services. The Medicines and Healthcare Products Regulatory Agency (MHRA) ensures that medicines and medical devices work and are acceptably safe<sup>13</sup> and the Healthcare Commission checks that healthcare services are meeting standards in a number of areas<sup>14</sup>.

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<sup>7</sup> Docteur and Oxley *Health-Care Systems: Lessons From the Reform Experience* OECD Health Working Paper, 2003 p. 8-9

<sup>8</sup> Abel-Smith and Mossialos, 1994, p. 10

<sup>9</sup> Ibid, 1994, p. 10

<sup>10</sup> Ibid, 1994, p. 58

<sup>11</sup> Ibid, 1994, p. 59-61

<sup>12</sup> <http://www.hta.nhsweb.nhs.uk/aboutHTA.htm>

<sup>13</sup> [http://www.mhra.gov.uk/home/idcplg?ldcService=SS\\_GET\\_PAGE&nodId=5](http://www.mhra.gov.uk/home/idcplg?ldcService=SS_GET_PAGE&nodId=5)

<sup>14</sup> <http://www.healthcarecommission.org.uk/homepage.cfm>

The National Institute for Health and Clinical Excellence (NICE) was established as a Special Health Authority in 1999 to promote the effective use of resources within the NHS. The Centre of Health Technology Evaluation at NICE develops guidance on the use of new and existing medicines based on clinical and economic evidence. Local government and NHS organisations are expected to take account of this guidance in order to achieve government targets, for example those set out in the 'Choosing Health' White Paper, and to act on recommendations as soon as possible. They are legally obliged to fund and resource medicines and treatments recommended by NICE's technology appraisals.<sup>15</sup>

There is clear evidence that HTA initiatives have a high level of impact on policy making especially those that emanate from the NHS Health Technology Assessment Program and NICE.<sup>16</sup>

Moves to boost openness on NHS drugs come at a time of growing criticism of NICE by patient organisations and pharmaceutical companies after a number of rulings which advised against the NHS paying for certain new medicines or treatments for patients. Recent scrutiny of NICE resulted in charges that, as evaluation processes are delivered from a primarily NHS perspective, life-extending drugs are refused on the basis of the limited resources of the health service and the need to make tough decisions based on cost-effectiveness rather than on assessment of the benefit that may be gained by the patient and society as a whole.<sup>17</sup> Societal costs associated with failure to treat severe illness such as illness-related unemployment and the consequent burden on social services are not taken into account.<sup>18</sup> The fact that preventing access to more costly medicines may save health budgets money in the short-term but not in the long-term, if the use of older medicines leads to a deterioration of the condition and a costly hospital stay is also overlooked.

The subsequent decision to boost transparency of NICE, by opening up the work of the Committee to public scrutiny, will put the UK ahead of practices adopted by equivalent agencies in other countries.<sup>19</sup>

## Denmark

Denmark's health system is financed wholly by taxation, with mainly public providers of health care. Every citizen in Denmark is covered by the provisions in the Healthcare Act, which offers total or partial coverage of expenditures for treatment as well as reimbursement for all pharmaceutical treatment for which the Danish Medicine's Agency has granted general reimbursement.<sup>20</sup> Public hospitals are financed directly by government who allocate annual budgets for local authorities' total expenditure, both on current and capital accounts. Hospital beds are over ninety percent publicly owned and counties are able

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<sup>15</sup> NHS NICE A Guide to NICE, April 2005

<sup>16</sup> Roehrig and Kargus, 2003, p. 36

<sup>17</sup> For an example of this see <http://news.bbc.co.uk/1/hi/health/6652183.stm>

<sup>18</sup> <http://www.rcpe.ac.uk/policy/archive/2007/inquiry-nice.php>

<sup>19</sup> <http://www.ft.com/cms/s/8a923270-04db-11dc-80ed-000b5df10621.html>

<sup>20</sup> LIF - The Danish Association of the Pharmaceutical Industry, 2007, p. 13

to indicate which parts of their county are open or closed for the entry of further specialists and general practitioners. Hence, the government has a high level of control over the provision of health care.<sup>21</sup>

The acquisition of new technologies is left to the five regions which own and run the hospitals. There is no price regulation of drugs; instead there has long been a positive list<sup>22</sup> and variable cost-sharing. Whilst consumption has remained static there has been an annual increase in cost by about 10%.<sup>23</sup>

Denmark's HTA system was established based on the understanding of political and health service decision makers that limited financial resources and an increasing demand for healthcare technologies made prioritisation unavoidable.

At the central level it is carried out by a HTA unit; The Danish Centre for Evaluation and Health Technology Assessment (DACEHTA) which exists within the framework of the National Board of Health (NBH). The NBH is in turn a part of the Health Ministry. This unit produces HTA and the regions follow suit.<sup>24</sup>. Among DACEHTA's key aims is improving value for money alongside quality and standards.<sup>25</sup>

In reality the HTA unit is fairly weak. The Ministry keeps a close watch on it in order to neutralise 'expensive' healthcare technologies, as their adoption results in requests for extra funding from the regions.<sup>26</sup> As a result of the healthcare settlement and the HTA system adopted, Denmark is a laggard, even in comparison to other European nations, in introducing and diffusing new pharmaceuticals and other healthcare technologies.<sup>27</sup> This is because HTA is closely linked to the government and very focused on curbing expenditure

## France

France, inspired by the ideology of Bismarck, enshrined health as a fundamental right in its Constitution of the Fifth Republic. However, the French healthcare system, unlike that of the UK and Denmark, is financed mainly by social insurance and delivered by a mixture of public and private providers. A fundamental principle of the healthcare system is the element of personal contribution and as such eighty five percent of the population is covered by complementary health insurance.<sup>28</sup>

The government controls the capital construction of all hospitals under the 'Health Map' plan, as well as the budgets of public hospitals, the purchase of medical equipment, the rates charged by private hospitals,

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<sup>21</sup> Abel-Smith and Mossialos, 1994, p. 11-130

<sup>22</sup> A positive list can broadly be defined as a list of drugs identified as suitable for reimbursement on the basis of their safety, efficacy, unique features (such as for rare diseases), and cost utility.

<sup>23</sup> Ibid, 1994, p 21-26

<sup>24</sup> <http://www.sst.dk/default.aspx?lang=en>

<sup>25</sup> [http://www.sst.dk/Planlaegning\\_og\\_behandling/Medicinsk\\_teknologivurdering.aspx?lang=en](http://www.sst.dk/Planlaegning_og_behandling/Medicinsk_teknologivurdering.aspx?lang=en)

<sup>26</sup> Interview with Michael Appel, CEPOS, 21<sup>st</sup> May 2007

<sup>27</sup> LIF - The Danish Association of the Pharmaceutical Industry, 2007, p. 3

<sup>28</sup> Abel-Smith and Mossialos, 1994, p. 10

the number of pharmacies per head and the price of drugs. It also has the power to ratify agreements between health insurance funds, doctors and other professionals.<sup>29</sup>

However, the public-contract model gives the French government less control over cost-containment than in the other states since reimbursement operates through insurers. While it can control the price of most medical services it has been unable to control the volume except with the limited effects of cost-sharing.

France has seen recent attempts to extend control over the cost of health care. In 1991, the government extended the 'Health Map' system, intended to limit supply, to the use, rather than just the acquisition of expensive medical technology in an attempt to increase government control on the supply-side.<sup>30</sup>

Recent reorganisation has resulted in the creation of a central High Health Authority (HAS) in 2005 which was given key authority for evaluating the medical benefits of drugs and determining pricing and reimbursement.<sup>31</sup> The creation of this body is set to raise the focus on cost-containment by bringing decision-making under closer government control.

This hybrid yet state-centric system impacts on how HTA works in France. Although there have been recent moves towards the evaluation of medicines through a central HTA body, overall it has had a modest impact on policymaking compared to other EU nations. France, compared to other European nations, has thus experienced a higher diffusion rate for new technologies.<sup>32</sup>

## Germany

As in France, the German health system is primarily financed by a system of social insurance with mixed public and private providers. All services are contracted rather than directly provided by the government. HTA decision making bodies in Germany therefore involve more than one provider and are composed of representatives of sick funds (insurers), doctors and the government.<sup>33</sup>

Around 10% of Germans choose to opt out of the public system. The ability to turn to private insurance forces the public sector to ensure that the service gap does not become too wide in order not to lose too many young, high income consumers with typically low health expenditures.<sup>34</sup> This has put the German government under increasing pressure to make its healthcare system more cost effective.

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<sup>29</sup> Ibid, 1994, p. 33-35

<sup>30</sup> Abel-Smith and Mossialos, 1994, pp. 33-35

<sup>31</sup> Arfwedsen, *Balancing Cost, Innovation and Availability in Health Care – A Guide to the Issues*, 2007, p. 5

<sup>32</sup> Roehrig and Kargus, *Health Technology Assessment in Canada and the G7 Countries: A Comparative Analysis of the Role of HTA Agencies in the Decision Making Process*, Working Paper produced by the Health Care System Division, 2003, p. 32

<sup>33</sup> Abel-Smith and Mossialos, 1994, p.10

<sup>34</sup> Prewo, W., *Germany: How Not To Organise a Health Care System in The Dangers of Undermining Patient Choice: Lessons From Europe and Canada*. 2006, p. 8

In the past, the German market was attractive to pharmaceutical companies, largely because up until 1989 it operated a free-pricing system. As such, access to medicines was relatively quick in Germany.<sup>35</sup> However, the pressure to plug the service gap between public and private healthcare expenditure on medicines meant that healthcare spending rose rapidly in Germany.<sup>36</sup> Since the introduction of a reference price system<sup>37</sup> in 1989, the long term aim of the Ministry of Health has been to reduce supply, in particular through the use of positive and negative lists, with more influence being given to sick funds to control costs.<sup>38</sup>

Due to the increasing focus on cost-containment to minimise the financial burden involved with the dissemination of new technologies, HTA has played an increasingly important role in German health policy since the 1990s. Increased reliance on HTA eventually resulted in the creation of the Office of Technology Assessment at the German Parliament in 1990.<sup>39</sup>

The Institute for Quality and Economic Efficiency in the Healthcare Sector (IQWiG) was established in 2004 in the course of the Healthcare Reform, with the primary goal of contributing to improvements in health care in Germany. It aids in HTA activities by investigating which therapeutic and diagnostic services are feasible and valuable and passing this information on to self-governing bodies.<sup>40</sup>

The major activity in the use of HTA is for the purpose of decision-making regarding the coverage of technologies in the benefits catalogue. Significant funding has been directed towards this purpose, of which the most significant source comes from the German Ministry for Health and Social Affairs.<sup>41</sup> Government-linked HTA bodies can refuse to allow a hospital to claim reimbursement for unauthorised use of new technology.<sup>42</sup>

## Canada

The Canadian health service is characterised by universality and single-payer funding derived from general tax revenues.<sup>43</sup> Canada is unique in that it is the only industrialised country where private health insurance schemes are outlawed.

The result of Canada's refusal to allow private insurance is that decision-makers involved in health care are acting within an environment that is increasingly dominated by considerations of cost-effectiveness.

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<sup>35</sup> Data Monitor *Pricing and Reimbursement in Europe: Can the Drive for Cost Effectiveness Overcome Cost Containment?*, 2006, p. 79

<sup>36</sup> *Ibid*, 2006, p. 79

<sup>37</sup> Under reference pricing, drugs are grouped by pharmacological equivalence. Generics and patented products are listed together and reference prices are set based on the difference between the cheapest and most expensive drugs. Innovative products are theoretically exempt from reference pricing. But in practice the government rarely makes an exception. And patients are rarely willing to pay more to obtain a high-priced drug.

<sup>38</sup> Abel-Smith and Mossialos, 1994, p. 21

<sup>39</sup> Sainfort, 2003, p. 28

<sup>40</sup> <http://www.iqwig.de/about-us.21.en.html>

<sup>41</sup> Sainfort, 2003, p. 28

<sup>42</sup> Abel-Smith and Mossialos, 1994, p. 20-23

<sup>43</sup> Roehrig and Kargus, 2003, p. 31

Governments work to reduce the availability of new products and implement mechanisms to limit their reimbursement.<sup>44</sup> This explains the particular growth of interest in HTA in Canada.

Because both provincial and territorial governments are responsible for the delivery of health care, bodies such as Quebec's Conseil d'évaluation des technologies de la santé and British Columbia's Office for Health Technology, have been established across the country in addition to the national Canadian Coordinating Office for Health Technology Assessment (CCOHTA) established in 1989.<sup>45</sup>

CCOHTA was made a permanent organisation in 1993. Its remit is to encourage the appropriate use of health technology and to strive to influence decision makers by collecting, analysing and disseminating information concerning the effectiveness and cost of technology.<sup>46</sup> Of all the Canadian HTA agencies, CCOHTA gives the most attention to costing, cost analysis and economic evaluation.<sup>47</sup>

Bodies with closer links to decision makers such as the CCOHTA, have a larger impact on decisions regarding the acquisition of new health technologies and the federal budget ensures that CCOHTA, as the only federal body, is well positioned to respond and contribute to the Canadian HTA strategy. In this way the adoption of new technologies is controlled by government through its selective engagement with pre-marketing controls.<sup>48</sup>

Because the adoption of new technologies is controlled by governments through HTA and the use of planning tools aimed at determining the distribution of technology<sup>49</sup>, Canada ranks very poorly in terms of access to high-tech machinery<sup>50</sup>. For example, in the year 1992-1993 the availability of Magnetic Resonance Imaging was 1.1 units per million people in Canada as opposed to 11.2 units in the US.<sup>51</sup>

## The United States

The US is exceptional among industrialised countries in terms of its healthcare settlement. Its private insurance/provider model of health care is financed by private insurers with private providers. However, the US still has a strong public element that covers the poor and elderly through its Medicaid and Medicare programmes which were enacted in 1965. Medicaid operates as a vendor payment programme. States may pay healthcare providers directly on a fee for service basis or through a variety of pre-payment arrangements. However, states do use cost-sharing devices on some Medicaid beneficiaries.<sup>52</sup>

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<sup>44</sup> Crowley, B. C Why Canadians pay less For Drugs than Americans in *The Dangers of Undermining Patient Choice: Lessons From Europe and Canada*, 2006, p. 26

<sup>45</sup> Battista, R. N and M. J. Hodge, *The Evolving Paradigm of Health Technology Assessment: Reflections For the Millennium*, 1999, p. 1464

<sup>46</sup> Roehrig and Kargus, 2003, p. 14

<sup>47</sup> Menon cited in Roehrig and Kargus, 2003, p. 25

<sup>48</sup> Ibid, 2003

<sup>49</sup> Ibid, 2003, p. 37

<sup>50</sup> Esmail and Walker, 2005 *How Good is Canadian Health Care? 2005 Report: An International Comparison of Health Care Systems Critical Issues Bulletin*, The Fraser Institute

<sup>51</sup> Moran and Alexander *Technology, American Democracy and Health Care* *British Journal of Political Science*, Vol 27, No 4, Oct 1997 p. 575

<sup>52</sup> [http://www.cms.hhs.gov/MedicaidGenInfo/03\\_TechnicalSummary.asp#TopOfPage](http://www.cms.hhs.gov/MedicaidGenInfo/03_TechnicalSummary.asp#TopOfPage)

In addition, the US is structurally unique because it is both a major producer and consumer of health care which means that both demand for and supply of medical technology is very high. Investment in new medical technologies is very high as is their levels of availability and rate of diffusion. This is demonstrated by cross-national examination of the comparative availability of selected medical technologies such as radiation therapy and open-heart surgery. Measured in units per million, the United States experiences levels of availability up to three times greater than in Canada and Germany.<sup>53</sup>

Significant historical factors have influenced this technological dynamism. The legacy of conflict in the twentieth century drove medical device innovation, transforming the simple medical goods industries into leaders in research and development. Post war state involvement, influenced by the economic power and regulatory expertise of the medical goods industries, was directed at funding research (whilst avoiding meddling with professional decisions) and shaping and creating markets by expanding regulatory jurisdiction.<sup>54</sup>

Prompted by state support for research and development, successful innovation created major industries which became vital to the wider economy. Hence, in the era of cost-containment, policymakers in the United States have nevertheless not attacked technological innovation.

There is a high level of disparity between the resources allocated to innovation and the resources allocated to assessment, and federal government commitment to HTA has been inconsistent. The National Centre for Health Technology (NCHCT) ceased to exist under President Ronald Reagan and the Office of Technology Assessment (OTA) ceased to examine healthcare-related technologies from a national perspective in 1995. The US therefore differs in its approach towards HTA with regard to the role the federal government is afforded in the decision-making process.<sup>55</sup>

Furthermore, bodies that do provide HTA differ in their approach to prioritising healthcare system goals when compared to Europe and Canada. In contrast to Europe, the US does not use price controls to contain healthcare spending because its system of reimbursement mechanisms and high level of patient co-payments provide a direct subsidy for drugs and treatment. Even the publicly funded element of the American healthcare system, reimburses providers for all treatments within categories that are 'reasonable and medically necessary' – a term interpreted to involve all care considered medically appropriate<sup>56</sup> and thus provides incentives for hospitals to invest in expensive technologies<sup>57</sup> Therefore, although the Agency for Healthcare Research and Quality (AHRQ) aims to reduce unnecessary costs, cost-containment is not its immediate priority. Instead, the focus of the organisation's strategic goals is to ensure the efficient transformation of research into practice.<sup>58</sup>

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<sup>53</sup> Moran and Alexander, 1997, p. 573

<sup>54</sup> Ibid, 1997, p. 585-586

<sup>55</sup> Perry and Thamer, 1999, p186

<sup>56</sup> Elhauge, 1996, p. 1546

<sup>57</sup> Moran and Alexander, 1997, p. 586

<sup>58</sup> <http://www.ahrq.gov/about/budgtix.htm#report>

Recently there have been moves towards increased investment in comparative effectiveness research, mainly due to the need to address the rising cost of health care, fuelled by the rapidly growing size of the Medicare and Medicaid programmes<sup>59</sup>. The 2003 Prescription Drug Comparative Effectiveness Act, which gained broad bi-partisan support, became the basis of a provision included in the Medicare Modernization Act and proposed legislation in the form of the Enhanced Healthcare Value For All Act which will enable healthcare providers to avoid treatment that may be ineffective or overly expensive.<sup>60</sup> Such moves signal an alarming trend towards cost-containment that could jeopardise the United States' strong overall performance in providing patient access to healthcare-related technologies.

### **The International Dimension**

Considerable attempts are being made to encourage cross-national HTA regimes that support the spread of best practice and the dissemination of HTA activities.

Since HTA activities began, there has been a desire to share knowledge and resources at an international level. HTA, as we have seen in the previous paper, is a multidisciplinary tool, and innovations come from all over the world. The subjectivity inherent in HTA means it has to rely not only on empirical research but also on trial and error and learning from case work; a sort of 'jurisprudence' of HTA. That is why an international information-sharing database is an indispensable tool in helping to overcome the complexity of health technology decision-making.

This desire to share knowledge has been particularly pronounced at the European level.

The European Commission has pushed for collaboration on HTAs, with the EUR-ASSESS programme, which took place from 1994 to 1997. Its aim was to promote coordination and communication in HTA among European nations in order to harmonise methods of technology assessments. EUR-ASSESS has created an informal network of people and organisations, improving the understanding of the work of others, improving the ability to focus the objectives of HTA, facilitating the sharing of experience and mutual learning opportunities, exchanging ideas on research agendas, and developing a common vocabulary. However, significant differences emerged in the expectations of different actors in European HTA, and in their perceptions of the impact of the project. These reflect the wide diversity of approaches existing in Europe.<sup>61</sup>

A number of other European projects are also worth mentioning, such as the International Information Network on New and Changing Health Technologies (EuroScan); a collaborative initiative

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<sup>59</sup> Banta, H. D and C. J Behney, 1981 Policy Formulation and Technology Assessment *The Millbank Memorial Fund Quarterly: Health and Society* Vol 59, No. 3, p. 458

<sup>60</sup> <http://tomallen.house.gov/index.cfm?ParentID=36&SectionID=52&SectionTree=3,22,36,52>

<sup>61</sup> [http://ec.europa.eu/health/ph\\_projects/1999/monitoring/fp\\_monitoring\\_1999\\_frep\\_09\\_en.pdf](http://ec.europa.eu/health/ph_projects/1999/monitoring/fp_monitoring_1999_frep_09_en.pdf)

by a number of HTA organisations to share information on important emerging technologies via an on-line database.<sup>62</sup>

More recently the European Collaboration for Health Technology Assessment/Assessment of Health Interventions (ECHTA/ECAHI) was created by the EU to improve coordination and communication between national activities on HTA.<sup>63</sup>

At an international level there have also been efforts to facilitate cross-national cooperation.

The first meeting of the Health Technology Assessment International (HTAi) was held in 1985 - at the time it was called the International Society for Technology Assessment (ISTACH). HTAi focuses solely on health technology assessment (HTA) and provides the key forum for all those from the worlds of health care, academia and business interested in the science, development and application of HTA.<sup>64</sup>

In 1993 the International Network of Agencies for Health Technology Assessment (INAHTA) was established by government-linked HTA agencies due to the evident need to cooperate and share information from different cultures. Today it comprises 45 members in 23 countries. Its role is to promote the work of different HTA agencies and inform the network of developments in the field. The members of the INAHTA – International Network of Agencies for Health Technology Assessment are predominantly wealthy and transition economies.<sup>65</sup>

## **Conclusion**

Medical technology has largely been created and marketed by market driven factors. However, states, bounded by democratic competition, adhere to certain 'rough and ready democratic principles' that lead to substantial differences in the character, size and structure of their healthcare-related markets.<sup>66</sup> For this reason the emergence of HTA systems and their purpose and structure is, to a great extent, a construct of the political economy of the country in which they originate.

What is particularly striking is the dichotomy between Europe and America. Unlike the US, European countries tend to have national health systems where acquisition of, and access to, new technologies is under government control. For these reasons it has proved expedient to establish HTA programmes supported by the national government. HTAs have had a clear impact on policymakers in Europe, particularly in Denmark and the United Kingdom, concerning the adoption and distribution of health technologies in their healthcare systems. By contrast, the federal government takes far less interest in

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<sup>62</sup> <http://www.euroscan.bham.ac.uk/about.htm>

<sup>63</sup> Roehrig and Kargus, 2003, p. 45

<sup>64</sup> <http://www.htai.org/>

<sup>65</sup> [http://www.inahta.org/inahta\\_web/index.asp](http://www.inahta.org/inahta_web/index.asp)

<sup>66</sup> Moran and Alexander, 1997, p. 578

HTA than in countries with nationalised health services and as a result HTA impacts less on healthcare decisions in the US.<sup>67</sup>

These differing HTA evolutions can be accounted for in terms of differing historical commitments to healthcare by national governments.

'The US government's first and most generous involvement in health care focused on expanding the supply of hospital centred, technologically sophisticated health care... In contrast to the United States, however, other Western countries have made the expansion of access their first and primary priority'.<sup>68</sup>

Europe is burdened by its historical commitment to expanding entitlement with the result that HTA is increasingly performed with cost-containment in mind. Interest in HTA in Europe and Canada has increased because of the need to justify expenditure on technology, particularly where countries lack their own domestic pharmaceutical industry, and because the combined pressures of ageing populations and more demanding consumers are exerting cost pressures on governments at the very same moment as the tax base is shrinking or static.<sup>69</sup>

Where consumers in the US have a wide range of drugs available to them European consumers are far more restricted in their choice. Although countries with nationalised health services believe that their healthcare systems prioritise the interest of citizens, HTA is in fact used as a precursor to supply-side restrictions on pricing and reimbursement.<sup>70</sup>

The implications for innovation are alarming, because; 'The technology we get reflects the incentive structure for using it'.<sup>71</sup> An incentive structure that encourages providers to trade off the costs and benefits of health care gives providers little incentive to use expensive technologies and thus researchers have little incentive to create it. HTA then has very little regulatory potential.<sup>72</sup> It holds within itself the possible cause of its eventual demise by stifling innovation and causing long-term harm.

It may be possible that EU member states and Canada can learn something from the US regarding the uptake and diffusion of healthcare-related technologies, particularly in an era where international bodies are looked to in order to facilitate the dissemination of HTA practice and results.

However, unless Europe and Canada move towards a significantly better-funded and more sustainable model of healthcare financing, HTA bodies, and their consequences for patients, are very much here to stay. These countries must face up to the necessity of moving away from healthcare models dominated by government funding in order to deliver to consumers the choice and empowerment they want out of

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<sup>67</sup> Roehrig and Kargus, 2003, p. 5

<sup>68</sup> Jacobs cited in Moran and Alexander, 1997, p. 574

<sup>69</sup> Sainfort, 2003, p. 29

<sup>70</sup> See <http://news.bbc.co.uk/1/hi/health/6652183.stm>

<sup>71</sup> Elhauge, 1996, p. 1526

<sup>72</sup> Elhauge, 1996, p. 1526

their healthcare systems.

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