



JULY 2009

Issue Brief

National Authority for Health: France

LISE ROCHAIX AND BERTRAND XERRI
HAUTE AUTORITÉ DE SANTÉ

The mission of The Commonwealth Fund is to promote a high performance health care system. The Fund carries out this mandate by supporting independent research on health care issues and making grants to improve health care practice and policy. Support for this research was provided by The Commonwealth Fund. The views presented here are those of the authors and not necessarily those of The Commonwealth Fund or its directors, officers, or staff.

ABSTRACT: The French National Authority for Health (Haute Autorité de Santé, or HAS) was established to assist France's public institutions in optimizing the basket of reimbursable goods and services and to help health care professionals continuously improve their clinical practice by defining best-care standards and identifying relevant tools and methods. HAS carries out single technology assessment (STA) and multiple technology assessment (MTA), assessing both the intrinsic benefit of the new technology and its effectiveness compared with that of existing technologies. A new treatment may not be covered unless it provides either improved benefit or lower cost, and STA is mandatory before a new drug, device, or medical procedure can be added to the benefit list for sickness funds. While HAS recommendations are advisory, the decision-making bodies (the Ministry of Health or the union of sickness funds) accept its findings in most cases.

★ ★ ★ ★ ★

OVERVIEW

The French National Authority for Health (Haute Autorité de Santé, or HAS) was created by the National Health Insurance Reform Act of 2004 and was established on January 1, 2005. HAS was established to assist decision-making by public institutions, with the goals of optimizing the basket of reimbursable goods and services and helping health care professionals continuously improve their clinical practice by defining best-care standards and identifying relevant tools and methods. It is an independent, scientific, public authority that has financial autonomy and a unique legal identity.

HAS brings together within a single entity a number of functions designed to improve the quality of patient care and to guarantee equity within the health care system. HAS's activities are diverse and range from assessment of drugs, medical devices, and procedures to publication of guidelines, accreditation of health care organizations, and certification of doctors. As part of that overall mission, HAS provides health authorities with the information needed to make decisions on the reimbursement of medical products and services, including assessment of drugs, medical devices, and diagnostic and therapeutic procedures that

For more information about this study, please contact:

Lise Rochaix, Ph.D.
Chair
Economic and Public Health
Specialized Committee
Board Member
Haute Autorité de Santé
l.rochaix@univ-aix.fr

To download this publication and learn about others as they become available, visit us online at www.commonwealthfund.org and register to receive Fund e-Alerts.

Commonwealth Fund pub. 1295
Vol. 58

are covered by National Health Insurance (NHI). HAS is not a government body. It is an independent public organization with financial autonomy and a Board appointed by government officials. HAS is mandated by law to carry out its mission and reports to Government and Parliament. It liaises closely with government health agencies, national health insurance funds, research organizations, unions representing health care professionals, and patients' representatives.¹ It has dedicated funding sources, most importantly a tax on pharmaceutical companies' advertising expenditures. This paper focuses on HAS's health technology assessment activities.

HAS carries out two kinds of health technology assessment (HTA): single technology assessment (STA) and multiple technology assessment (MTA). STA is initiated at the request of a drug or device manufacturer or a professional society for medical procedures. STA is mandatory before a new drug, device, or medical procedure can be added to the benefit list for sickness funds and is used for pricing decisions. HAS assesses both the intrinsic benefit of the new technology and its effectiveness compared with that of existing technologies. A new treatment may not be covered unless it provides either improved benefit or lower cost. While HAS recommendations are advisory, the decision-making bodies (the Ministry of Health or the union of sickness funds) accept its findings in most cases. STAs are produced rapidly—within an average of 73 days for new drugs.

MTA reviews an entire class of drugs, devices, or procedures. Recent examples include a review of Alzheimer's drugs and a report on strategy for the management of carotid stenosis. MTAs can also take the form of guidelines on public health interventions (screening) or issues in the organization of care. MTA projects may be initiated by HAS, but usually stem from requests from public agencies or other interested parties. The scope of the assessment and appropriate methods are developed in consultation

with stakeholders; in addition to clinical benefits, assessments may address economical, ethical, and legal aspects of the study topic.

Legislation in 2008 gave HAS the new mission of conducting economic assessments. These include cost-effectiveness comparisons of specific products, as well as more global studies of the value to the community of different health strategies and technologies. Economic evaluations will generally be part of MTA, rather than STA, projects. To conduct these studies, HAS has established a new department with an independent oversight committee.

PRINCIPLES AND VALUES

The approach taken by HAS can be characterized as:

- *Integrated.* HAS takes a global approach to disease management and quality in health care, covering a large number of fields, including technology assessments, clinical guidelines, hospital certification, quality improvement initiatives in health care at both macro (hospitals, networks) and micro (health professionals, patients) levels, external evaluations of organizations, and development of public health strategies such as screening policies;
- *Scientific.* As a scientific body, HAS must use the principles of evidence-based medicine and ensure that its products are developed with methodological robustness and rigor. This requires the use of appropriate and up-to-date expertise in all fields of evaluation;
- *Transparent.* Both the methods used and the advice given are made publicly available;
- *Inclusive.* HAS strives to include all stakeholders (professionals, patient representatives, decision-makers, medical technology manufacturers) at various stages in the production of advice, opinions, and guidelines;
- *Impact-based.* HAS must assess the relevance and impact of its decisions and advice in terms

¹ "Haute Autorité de santé (HAS): About Us", http://www.has-sante.fr/portail/jcms/c_5443/english?cid=c_5443, accessed on June 3, 2009.

of professionals' behavior as well as medical outcomes, when possible;

- *Independent.* HAS's products, whether developed internally or externally, are reviewed by independent scientific specialist committees whose members are drawn from clinicians, professional groups, researchers, and patient and public representatives. HAS is independent from government or from other bodies requesting advice;
- *Up-to-date.* All HAS products are updated at regular intervals (three to four years, or earlier if new evidence becomes available); and
- *Timely.* Timeliness is increasingly important for HAS and new methods are currently being developed for rapid responses.

STRUCTURE, SIZE, AND OUTPUTS

HAS employs approximately 400 full-time staff, of whom about 80 are dedicated to health technology assessment. In addition to its full-time staff, HAS works with 34 regional project leaders (who are involved in assessment activities), 734 surveyors, and over 3,000 external consultant experts and health care practitioners.

The HAS Board is the organization's deliberative body and is accountable for the rigor and impartiality of HAS's output. It is responsible for programming, steering, and implementing the missions

assigned to HAS by law and for developing its strategy. The Board is composed of eight members, appointed for six year terms, renewable one time. Two members are proposed by each of the following: the President of the Republic, the Speaker of the Senate, the Speaker of the National Assembly and the Chair of the Economic and Social Council. Seven specialist committees, each chaired by a board member, are responsible for examining proposed findings prepared by the HAS operational departments.

In 2008, the HAS operating budget was € 71.7 million; actual spending was € 66 million. Although HAS is a public entity, it has its own revolving fund, and most revenues do not come directly from the government. The largest income sources are proceeds from a tax on pharmaceutical companies' advertising spending and funding from the health insurance fund.

In 2007, HAS committees issued over 1,200 assessments of specific health treatments, including:

- 940 opinions about drugs (267 for a first listing, 41 for a new indication, the remainder dealing mainly with renewals);
- 236 opinions about devices and health technologies; and
- 83 opinions about medical and surgical procedures.

It also issued a number of multiple technology assessments, economic assessments, and public health guidelines.

Table 1. Sources of HAS Income, 2008

10% of proceeds from the tax on pharmaceutical company spending on advertising	47%
Fees from manufacturers	8%
Contribution from the health insurance fund	33.5%
Government subsidy	6%
Miscellaneous (investment income)	4%

Source: HAS 2008 annual report.

USING COMPARATIVE EFFECTIVENESS RESEARCH TO INFORM POLICY DECISIONS

Health technology assessment activities at HAS deal with public health interventions, drugs, medical devices, and medical and surgical procedures.

Increasingly, HAS strives to enlarge its appraisals, beyond clinical effectiveness, by including, when judged relevant, economic, societal, ethical, organizational, and judicial dimensions.

HAS carries out two kinds of health technology assessment (HTA) activity: single technology assessment, focusing one drug or other treatment, and multiple technology assessment, which reviews an entire class of drugs or devices. Single technology assessments account for about 80 percent of drug assessment activity, 20 percent of medical device assessments, and 50 percent of procedure assessments.

Single Technology Assessment (STA)

HAS assessment is mandatory before inclusion of any new health technology on the health insurance benefit list. This applies to drugs, devices, equipment, biological tests, and medical and surgical procedures. Based on the assessment, HAS gives an “opinion” on the *expected* or *actual benefit* provided by the technology, as well as on the *improvement in expected benefit* (assessment of relative/comparative effectiveness) in regard to a standard comparator (comparative effectiveness). The opinions issued by HAS support coverage and reimbursement decisions, as well as decisions on the pricing of both health products and procedures. Its assessment may also be required for modifications to coverage conditions, such as new indications for technologies already listed.

HAS opinions on pharmaceutical products and medical devices are forwarded to the Ministry for Health and Social Security. Based on HAS conclusions, the Minister decides whether or not to reimburse the products, and the committee in charge of setting prices at the Ministry negotiates a price/volume contract with the manufacturer. The current regulatory requirement is that “medicines that neither provide a therapeutic added value (as assessed by HAS) nor cost

savings” may not be included in the list of reimbursed products. As a consequence, products for which HAS recognizes no added value can only be reimbursed if they are less costly than comparators. The pricing committee may grant a higher price than comparators for drugs that produce an improvement in actual benefit.

For procedures and biological tests, coverage and pricing decisions also reflect HAS advice, but are made by the national sickness funds union, which represents the three largest health insurance funds—CPAM, the mandatory fund for salaried employees, and the separate funds for the self-employed and for farmers.

Depending on the type of technology, a reassessment may be planned at regular intervals (every five years for drugs, within five years for medical devices, and variable for procedures) for renewal of coverage decision.

Multiple Technology Assessment (MTA)

HAS produces assessments of therapeutic classes of drugs or categories of medical devices/equipment. It also produces public health intervention assessments and reports on issues related to the organizational dimensions of the health system. In general, MTAs clarify strategic choices, allow redefinition of conditions of use, and support a more global approach to structural decisions regarding coverage policy, health care delivery, or health care organization.

The following list gives examples of MTA projects recently conducted by HAS (all reports are available on the HAS Web site):

- Alzheimer’s drugs review
- Medical devices: total hip prostheses, wound dressings, self-monitoring glycemia devices, cochlear implants, implants for wall repair in genito-urology and digestive surgery, cardiac pacemakers
- Third-generation oral contraceptives
- Strategy for the management of carotid stenosis: indications for revascularization techniques

- Cardiac surgery with or without extra-corporeal circulation: role of the second surgeon
- Dental prostheses with a ceramic structure
- Sleeve gastrectomy for morbid obesity
- Tension-free vaginal tapes
- Lumbar disc prosthesis

PROCESSES AND METHODS

Topic Selection

STA activity is determined by applications submitted by the pharmaceutical or medical device industry or, in the case of procedure assessments, by professional associations. All new drugs and devices and all new indications for existing treatments are submitted to HAS before inclusion on the reimbursement list.

Unlike STA activity, MTA activity is planned on a yearly basis, following a work program definition process. This process includes several steps: customers' solicitation, selection criteria definition, proposal and validation by internal decision bodies, definition of reporting modalities of the final program content, as well as implementation follow-up. Although HAS has the right to self-select topics, most of the MTA work program is based on requests by public institutions (sickness funds, general directorates at the Ministry for Health and Social Security), academic societies, and patients' associations.

This work program is now defined simultaneously and in coherence with other HAS activities, such as accreditation. The global objective is to create the best interaction possible between HTA activities and the guidelines and evaluation systems applied to health professionals' practices or health care organizations.

Methods

For STA, assessment is based on evidence from companies, when relevant, literature reviews, and other relevant data sources. Internal assessments, focusing on clinical effectiveness, target population definition, and condi-

tions of use for already reimbursed technologies are validated by external clinical or methodological experts.

An opinion is then given by one of the specialized committees, focusing on two criteria:

- The *intrinsic value* of the drug, device, or procedure, based on effectiveness assessment. The actual benefit represents the combined assessment of the severity of the medical condition treated, the efficacy/safety ratio (clinical impact), the expected positioning of the product within the existing therapeutic strategy, and the product's public health impact. The HAS opinion specifies whether the actual benefit is sufficient to justify reimbursement.
- The *therapeutic improvement* in actual benefit, based on a relative effectiveness assessment, provided by the product. The clinical improvement brought by the product, relative to existing therapies, is assessed on a five-level scale, ranging from level I (major improvement) to level V (no improvement).

The opinion is sometimes accompanied by a request for post-launch studies, in order to provide useful data at the time of reassessment regarding conditions of use or reasons for discontinuation. The final opinion is sent to decision-makers (Ministry for Health and Social Security, union of sickness funds).

To promote timeliness, HAS has defined several different types of assessment procedures. There is a choice between simplified versus full-scale assessments, depending on the complexity of the topic. A fast-track procedure has also been implemented for innovative drugs. The STA process must be performed within timelines set by law. For medical devices and drugs, the target is 90 days from the initial application to the final opinion; for procedures, the timeline is 180 days. In 2007, the mean delay was 73 days for drugs and 142 days for medical devices.

For MTA, the HAS methodology follows international standards for technology assessment. For a selected topic, several steps are followed:

- A scoping process involving the main stakeholders, to define relevant aspects to be assessed. In general, clinical effectiveness, harms, and conditions of use are systematically assessed. According to the topic, economical, ethical, legal, and societal dimensions may also be assessed.
- Definition of the most appropriate method for the assessment of the selected aspects.
- Critical review of available evidence (selection of published data according to the level and quality of evidence).
- Consultation with experts, using working group meetings, formalized experts' consensus, or the Delphi method (a systematic, interactive [forecasting](#) method that relies on a panel of independent experts).
- Production of a first version of the assessment report, peer review when necessary, and appraisal and final opinion by the relevant specialist committee.
- Validation by the HAS board and publication on the HAS Web site.

Economic Evaluation

Although a small number of economic analyses have been conducted in the past by HAS and one of its precursor agencies, legislation in 2008 entrusted HAS with the explicit mission of issuing “recommendations and medico-economic opinions on the most effective strategies of care, prescription, and disease management.” Economic evaluation has thus been declared as one of the tools to be used by HAS in aiding public decision-making. This applies to health actions and program evaluation, as well as to reimbursement decisions for health products.

The economic analyses conducted by HAS help underline the opportunity costs associated with reimbursement decisions and contribute toward making the use of reimbursable goods and services more efficient. Over time, economic evaluation should also become useful to medical professionals in their attempt to prescribe health care resources more efficiently.

Three types of economic assessments are produced:

1. When strategies are identical both in terms of medical efficacy and tolerance, the least expensive strategy is recommended. The economic calculation may involve a simple comparison of prices of a daily treatment—for example, the treatment of arterial hypertension with angiotensin-converting enzyme (ACE) inhibitors versus angiotensin II receptor antagonists (ARBs). Or it may involve modeling of the costs of an entire disease management pathway.
2. When a difference in efficacy or patient tolerance is identified, the economic evaluation takes into account both outcomes and costs, thus valuing the cost of the efficacy increase. Examples include published work on the role of immunological tests in screening for colorectal cancer and several studies currently under way, including assessments of statins, of noninvasive measures of hepatic fibrosis, and of the role of systems of self-measurement in the follow-up of patients treated with the anticoagulant VKA. HAS could also consider requesting additional economic data when post-marketing studies are undertaken.
3. For a limited number of topics, a full-scale MTA is carried out in order to measure the added value to the community of health strategies, products, and technologies. An example of such a topic is the use of human growth hormones in children. This global approach will strive to document, beyond economic aspects, other considerations regarding organizational, social or ethical aspects.

The choice of intervention level is made on the basis of a systematic list of criteria.

Assessments are conducted by a new department of HAS, the economic evaluation and public health service, either internally or using outside experts. The intention is to develop a network of collaborating research centers over time. Work is overseen by a new interdisciplinary committee for economic and public health evaluation, which offers guidance during the scoping phase, examines potential conflicts of interest, and evaluates the scientific quality and ethics of completed work. The 25-member committee includes health professionals, patients' representatives, and experts representing eight different disciplines (economics, public health, management, administration, epidemiology, pharmacology, sociology and philosophy). HAS distinguishes the clinical evaluation of services from the economic evaluation phase, while ensuring they are complementary. The clinical evaluation remains the responsibility of the specialist committees for drugs, medical devices, professional procedures, and professional guidelines.

HAS made the decision to respond promptly to its new mission, rather than wait for methods to be fully stabilized. It will pragmatically develop its own methods while exchanging with its foreign counterparts. Methodological guides will be made available progressively. Transparency of methods and opinions is ensured by consultation of the stakeholders: payers, patients, health care professionals and representatives from industry.

As a general rule, economic assessments will be included in MTAs rather than in STAs. Consequently, pricing decisions for new technologies on the basis of STAs will not be modified by the new HAS activity. Expected impact on prices will be mainly the results of reexamination of a class of treatments through MTAs. The HAS purpose in producing economic assessments is also to assist health insurance funds in their effort to encourage more efficient use of health care resources.

Appeal

All guidance reports issued by HAS are submitted to product sponsors before a final version is issued.

Companies have the right to appeal by sending, within eight days, either written comments or a request for a hearing to the committee that produced the guidance. Opinions may be changed after consideration of the arguments raised by the company/companies. After a decision has been made on the basis of HAS guidance, companies may appeal to the supreme administrative court (Conseil d'Etat).

Conflict of Interest Policies

To carry out assessments, HAS recruits experts and uses an internal guideline for the management of conflicts of interest. A transparent process has been put in place to deal with this issue, with a screening phase of experts' CVs, rejection of experts with major conflicts of interest, announcement of potential conflicts during committees' meetings, and disclosures of these conflicts in the minutes of the committee meetings. All declarations of interests (internal and external experts) are made public on the HAS Web site. To prevent conflicts of interest and comply with ethical principles, an independent group of external experts on "ethics and independent expert opinion" was created in 2007. An ethical charter has been prepared and will be issued shortly.

Consultation with Stakeholders

Beyond regular consultation with stakeholders both during the annual work program definition and the hearings for specialist committees, HAS has recently experimented with external public consultation through its Web site on two topics: chronic disease management and task delegation between health professionals.

Dealing with Uncertainty

When issuing an opinion on a new technology, HAS may request that post-coverage observational studies be carried out. Questions may relate to conditions of use of products or, when justified by residual clinical uncertainty, to their effectiveness under real-life conditions, reasons for treatment discontinuation, or safety

issues. (In the case of safety questions, the study's objectives are shared with the French drug regulatory agency in the context of risk management plans.)

Access to Innovation

HAS has developed various actions to improve access to innovation in terms of timeliness and quality of evaluation. HAS can use fast-track procedures, prioritize the assessment of high-value technologies, and recommend conditional coverage with a requirement for prospective data collection, within well-defined conditions of use, performed by well-identified teams with specific skills in a selected number of centers. This mechanism enables decision-makers to closely monitor innovative technologies and to manage their diffusion. It ensures, at the same time, the generation of additional evidence to further reduce uncertainty.

For procedures, there is a well-defined regulatory framework, within which HAS can specify the type of data that should be collected while a temporary conditional coverage is granted. However, implementation of this mechanism has so far been poor, mainly because of a lack of financing sources for clinical studies and a lack of linkage with research programs. This framework will probably be extended to cover medical devices, with some of the operational issues addressed, starting in 2009.

For drugs, no comparable formal "research only" framework exists. However, drugs are reassessed within five years of their approval at the latest, and often sooner if significant new information becomes available to HAS. For innovative drugs that are authorized at an early stage of development, clinical trials are still ongoing at the time the drug is licensed, and the company has to submit its results to HAS as soon as they are available, leading to a reassessment of the product.

IMPACT ON POLICY AND PRACTICE: SELECTED CASE STUDIES AND OVERALL TRENDS

The impact of HTA products on the health care system is difficult to measure. Yet there are many examples of HTA reports that have had a real impact on French health policy, especially in the field of public health.

The majority of the decisions made by the Ministry of Health and sickness funds reflect the STA opinions delivered by HAS specialist committees dedicated to drug, device, and procedure assessments. It is estimated that more than 95 percent of HAS positive opinions regarding the reimbursement status of a new technology are followed by decisions to reimburse that technology. Negative opinions are, in the case of new technologies, followed in almost all cases. One exception was the response to HAS recommendations regarding the delisting of existing drugs.

From 1999 to 2001, all medicines qualifying for reimbursement were reassessed, at the request of the Ministry for Health and Social Security. Over that period, the HAS Transparency Committee examined 4,490 medicines and concluded that 835 of them showed insufficient benefit to warrant reimbursement. The reimbursement rates for those medicines with insufficient benefit were first reduced. It was then decided to update the reassessment. The products were reassessed by the Transparency Committee from 2003 to 2006. Altogether, HAS proposed the delisting of 370 drugs, of which 322 were delisted by decisions of the Minister for Health and Social Security. The Minister decided to retain 48 drugs, mainly vasodilators used to treat "cerebral insufficiency" in the elderly population, on the positive list. This mixed experience reflects, on the one hand, the high impact HAS opinions have on decision-makers; at the same time, it can be seen as reflecting the independence of HAS within the policy process.

ABOUT THE AUTHORS

[Lise Rochaix, Ph.D.](#), is a member of the Board of the French National Health Authority (HAS, Haute Autorité de Santé) and chairs the technology appraisal committee in charge of economic and public health evaluation (CEESP, Commission d’Evaluation Economique et de Santé Publique). She is currently in secondment from the University of Aix-Marseille II where she holds a chair in the economics department. Her research interests include regulatory issues in the health care sector and equity measurement. She earned her Ph.D. from York University, U.K. She can be e-mailed at l.rochaix@univ-aix.fr.

[Bertrand Xerri, M.D.](#), is deputy director to the Health Technology Division of the French National Health Authority (HAS, Haute Autorité de Santé). He has been involved in health technology assessment activities since 1999. He earned degrees in medicine and biology from the University of Paris 6. He can be e-mailed at b.xerri@has-sante.fr

ACKNOWLEDGMENTS

The authors would like to acknowledge Laurent Degos, Francois Meyer, and Margaret Galbraith for their contribution to this report.

Editorial support was provided by Paul Frame.

