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French HTA and appropriateness of care: Beyond reimbursement

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ABSTRACT

Heath Technology Assessment (HTA) is mainly used for reimbursement/disinvestment and access to innovation purposes. In addition, HTA is a useful tool to promote appropriateness of care, as it describes the updated level of validation of assessed health technologies. Thus, several tools (proper use sheets, drug-indexed decision support systems, supervision of practices or use) based on HTA are developed to promote the appropriateness of use of drugs, medical devices or diagnostic and therapeutic procedures among healthcare professionals.

HTA can also support the development and the update of clinical practice guidelines (CPG) which are the main tool of clinical practice improvement. In addition, HTA can increase CPG implementation through reimbursement of recommended health technologies. Therefore, HTA and CPGs can be perfectly articulated to enable synergistic synchronic or asynchronic action to improve the relevance of care by enabling more dynamic and efficient actions, particularly in terms of robustness and updating.

However, HTA shares with CPGs the same difficulties of implementation in the field. To face them, whatever the implementation strategy defined, it requires a multifaceted approach involving iterative communication and the involvement of healthcare professionals, patients and stakeholders, both upstream and downstream of the HTA stages.

1. HTA, a cornerstone of clinical practice improvement

According to the International Network of Agencies for Health Technology Assessment (INAHTA), « *HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making to promote an equitable, efficient, and high-quality health system* »[1]. In France, as in other countries, HTA is mainly used for reimbursement/disinvestment and access to innovation purposes. In addition, HTA is a useful tool to promote appropriateness of care, as it describes the updated level of validation of assessed technologies (medicines, medical devices, diagnostic and therapeutic procedures, vaccines, etc.) and particularly their conditions of use, as illustrated by the examination of the technical characteristics (TEC) domain of the European Network of HTA (EUnetHTA) HTA Core model [2]. Thus, HTA contributes to inform healthcare professionals and patients on the appropriateness of use of health technologies. HTA can also support the development and the update of clinical practice guidelines (CPG) which are the main tool of clinical practice improvement.

Abbreviations: ANSM, agence nationale de sécurité du médicament et des produits de santé (the french national agency for medicines and health products safety); ARS, agences régionales de santé (french regional health agencies); ATIH, Agence technique de l'information sur l'hospitalisation (technical agency for information on hospital care); CIR, Commission impacts des recommandations (committee on the impact of recommendations); CNEDIMTS, Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (the national committee for the evaluation of medical devices and health technologies); CPG, Clinical practice guidelines; CT, Commission de la transparence (transparency commission); DDSS, Drug-indexed decision support systems; DMD, Digital medical devices; DPD, Dihydropyrimidine déshydrogenase; EBM, Evidence-based medicine; EUNETHTA, European network of health technology assessment agencies; HAS, Haute autorité de santé (the french national health authority); HTA, Health Technology Assessment; INAHTA, International Network of Agencies for Health Technology Assessment; INCa, Institut National du Cancer (The French National Cancer Institute); MA, Market authorization; MD, Medical Device; PSPH, Etablissements Privés participant au Service Public (private hospitals participating to the public service); SBP, Service des Bonnes Pratiques (department of Good Practice Recommendations)

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1.1 HTA and appropriateness of use

1.1.1 Drugs

The French National Authority for Health (Haute Autorité de Santé —HAS) provides healthcare professionals with information on the essential factors that enable doctors to choose a drug for rational use: its certainty of evidence, clinical benefit, and therapeutic progress compared with another drug. For reimbursable medicines, the Transparency Commission (*Commission de la Transparence*, CT) issues a public opinion on whether each drug should be reimbursed by the national health system. This opinion indicates the therapeutic value of a drug, known as its Clinical Benefit, which includes a potential public health interest. It also provides information on the certainty of evidence based on a critical analysis of the available clinical data. Finally, it mentions the therapeutic progress of a drug compared with clinically relevant comparators, known as Clinical Added Value. When a new drug is authorised, the opinion of the CT offers an objective, independent, scientific critical overview of the drug's positive and negative aspects, in the light of various communications from pharmaceutical companies. The CT also determines the position of the new drug within therapeutic strategy. It can also limit the prescription of the new drug to dedicated prescribers when required or specify the conditions of packaging of the product. These opinions serve as benchmarks to promote the proper use of medicinal products by providing prescribers with criteria to base their choice on.

The proper use of medicines is promoted by health institutions, healthcare professionals, and pharmaceutical companies and is significant for both individual health and for public finances. Healthcare professionals are the primary recipients of messages about proper medicine use. It is therefore essential that reference information on the drug is both available and accepted by prescribers to ensure that the most effective and least dangerous treatments are implemented and to address patients' legitimate questions. Patients are thus becoming increasingly involved in HTA. The notion of active patient/healthcare system user is gradually replacing the notion of passive patient, especially since the COVID-19 pandemic and the implementation of vaccination plans. This better-informed patient-healthcare system user is now challenging therapeutic practice with robust scientific and experiential knowledges. In the context of health democracy, the patient-consumer is taking on greater responsibility for the sensible use of healthcare products.

While everyone agrees on the issue of the proper use of medicines, this is often defined in contrast to misuse. This primarily refers to prescriptions outside the scope of the Marketing Authorisation (MA) and outside the indicated uses. Complying with the indications, dosage and duration of treatment, as well as being aware of adverse effects, contraindications, drug interactions and precautions for use —particularly in the most vulnerable populations—can sometimes be a real challenge. The use of a medicinal product outside the scope of studies conducted by laboratories should not be hastily classified as misuse. Clinical studies include hand-picked populations under close monitoring before any MA application. These populations do not reflect usual practice patients, whether in terms of age—especially children, for whom data are often lacking —or comorbidities.

Indeed, physicians sometimes face with patients who are no longer clinical study subjects and who may have variable treatment compliance levels, leading to poor management of their condition. To deal with these conditions, physicians can prescribe drugs outside the scope of MA [3]. For some drugs, their prescription outside MA can also be secured by legal derogatory prescription framework (e.g., compassionate use framework).

Health institutions frequently remind healthcare professionals that using a medicine outside its MA's scope can mean venturing into unfamiliar territory, which may be dangerous for the patient and legally risky regarding medical liability. This advice of caution might be misunderstood/underestimated by the medical profession, which relies on its experience, and by the patient who cannot accept a lack of care, especially when it comes to medicines, particularly in France.

1.1.2 Diagnostic/therapeutic procedures and medical devices

As part of its evaluation for reimbursement purposes, HAS assesses the clinical, organizational Benefits and Added Value of medical devices (MDs) for individual use or diagnostic/therapeutic procedures by indication or group of indications. In addition to these two dimensions, the assessment must also specify the conditions under which it was carried out. In the case of diagnostic/therapeutic procedures, the HAS opinion must specify the methods of carrying out the procedure and any other information useful for the appropriate use of the procedure [4]. It should be noted that the conditions for performing a specific procedure or discipline may be the subject of dedicated assessment by HAS (e.g., conditions of use for dental implantology, specifications for instrumental abortion outside health care facilities). Beyond the HTA carried out by the HAS, this information may also be included in the reimbursement decision by UNCAM, the French National Health Insurance, which may mention the indications (therapeutic or diagnostic) as well as the specific conditions for prescribing, using or performing the procedure [5].

For MDs, the opinion of the HAS also specifies the conditions of use (technical specifications, special conditions of prescription) and rules on the compatibility of the conditions of use with the packaging of products [6].

For Digital Medical Devices (DMDs), specific pathways have been created since 2023. These pathways target DMDs with a therapeutic purpose or medical telemonitoring MDs. In this new context, the opinion of the HAS sets out a national framework for users (technical requirements including collecting accessories, minimal requirements for medical remote monitoring operator, recommendations on prescribing, use, supply, and the duration of patient monitoring [7,8]).

1.2 Tools for appropriateness of health technologies: proper use sheets

1.2.1 Drugs

The drafting and updating of proper use sheets are a statutory task of the HAS [9]. The purpose of these sheets is to define the place of drugs in the therapeutic strategy (except drugs targeting cancers, for which drafting and updating of proper use sheet are performed by French National Cancer Institute, InCa).

The main purpose of a proper use sheet is to inform prescribers on the risk of misuse of a reimbursable medicinal product or a class of reimbursable medicinal products. More specifically, it aims to draw the prescriber's attention to products likely to be prescribed to a wide population outside the reimbursable indications or the therapeutic strategy recommended by CT.

These sheets are usually 2 to 6 pages long (Fig. 1) and focus on one drug or a class of drugs by pharmacological group (e.g., proton pump inhibitors) or targeting a particular condition (e.g., severe asthma). A brief chapter highlights the essential information for proper use, including key messages specific to each medicine or class of medicines. The information presented here may include clinical data about the medical service provided which has limited the scope of reimbursement, or data related to the improvement of the medical service. It may also include information on a drug's effect size, allowing the therapeutic contribution to be assessed from a practical standpoint for both the prescriber and the patient. This document also provides information on the place of the medicinal product or class of medicinal products in the therapeutic strategy. It is designed to give a brief overview of the general management of the condition, and then specify its place in the therapeutic arsenal. Finally, other sections may be added according to the different messages to be promoted, covering efficiency, tolerance, eligible population for treatment, and risks for some populations. These sheets are based on the opinions of the CT and on MA criteria.

Fig. 1. Examples of proper use sheets on health products and diagnostic procedures.

The primary target audience for these guidelines is general practitioners, with secondary targets including other healthcare professionals, particularly medical specialists, depending on the therapeutic area of the medicinal product. Some sheets may be restricted to hospital prescribers, such as the one on therapeutic plasmas, or to patients, such as the sheet on HIV pre-exposure prophylaxis.

The medicinal products to be covered by a proper use guideline are selected by the CT or by the Board of the HAS (decision making body of HAS). The latter may also be asked by the Ministry of Health to draft a sheet. The choice is guided by the medicines reviewed by the CT. The current selection criteria are as follows: new therapeutic class (or new indication), high probability of use outside reimbursable indications, which could lead to an imbalance in the benefit-risk ratio or loss of chance due to the absence of the effect provided by another treatment, and excessive financial cost. The selection criteria are therefore linked on the one hand to widespread use in the population targeted by the medicine or class of medicines and, on the other hand, to the risk of misuse, particularly considering reimbursable indications and the recommended therapeutic strategy.

The main limitation of these sheets is their small number. Since 2005 (creation date of HAS) only 28 fact sheets have been published on the HAS website. Nevertheless, they can be relevant for a substantial proportion of the French population. For example, the fact sheet on proton pump inhibitors may be relevant to a quarter of the French population, taking at least once a year one medicine of this therapeutic class.

The impact of these guidelines can be measured by the number of citations in the medical and general press. For instance, the sheet on proton pump inhibitors was cited in nine general press articles and five medical press articles. The information sheet on severe asthma was mentioned in three medical press articles. These figures illustrate the significant effort required to bring about meaningful change in clinical practice. In addition, the impact can also be measured by the implementation of dedicated measures by UNCAM towards healthcare professionals, based on proper use sheets.

1.2.2 Diagnostic/therapeutic procedures and medical devices (MD)

Similarly to drugs, proper use sheets for MD or diagnostic/therapeutic procedures are drawn up based on the HTAs for these technologies and then discussed with stakeholders. The selection of procedures or MD to be covered by a proper use sheet is made by the HAS Board or National Committee for the Evaluation of Medical Devices and health technologies (CNEDiMTS) if the HTA has identified a significant risk of inappropriate use.

For MD, sheets are comparable to those for drugs, as they are often focused on a class of medical devices (e.g., dressings for sutured wounds, haemostatic pads for surgical use) and include information on best strategy for choosing products, role in therapeutic strategy, contraindications and conditions of use (Fig. 1). To date, 13 sheets have been published on MD.

For diagnostic/therapeutic procedures, sheets are 2 pages long, focused on one or two procedures, and report elements of appropriateness of use: indications, non-indications and role in diagnostic/therapeutic strategy. To date, 26 sheets have been produced on diagnostic/therapeutic procedures (mostly on imaging and medical biology).

Noteworthy, in addition to proper use sheets, CNEDiMTS also produces information documents on MD intended for professionals on the assessment and guidelines for prescribers and relating to the use of products [10].

1.3 Tools for appropriateness of health technologies: drugs-indexed decision support systems

In addition to the proper use sheets, which are available as web pages or printable versions, there are computerised systems that contribute to the proper use of medicines. These include drug-indexed decision support systems (DDSS).

A DDSS is a decision-making algorithm derived from a reference document (e.g., a drug use guideline) and designed to be integrated into prescribing and dispensing assistance software [11,12]. It appears in the software at the time of prescribing or dispensing, as an

information message triggered according to the patient's drug treatment and patient's characteristics. The aim of a DDSS is to reduce iatrogenic drug use and limit misuse. The applicant for a DDSS may be a health agency (INCa, ANSM), the Ministry of Health, the National Health Insurance, or the HAS. Requests for listing a DDSS are examined by the HAS based on their public health interest and the feasibility of building an appropriate algorithm and a short message displayed in a pop-up window.

The HAS makes DDSS available to publishers of healthcare software and medicinal product databases in the form of knowledge-structuring sheets, promoting their integration into prescribing and dispensing assistance software. The aim is to make the prescription of medicines safer as well as preventing and managing adverse effects. For example, Ozempic (semaglutide) prescription in type 2 diabetes shows that assistance software displays the following message: "Ozempic should only be prescribed to patients with inadequately controlled type 2 diabetes, in accordance with its marketing authorisation".

DDSS may also introduce the use of predictive companion tests to secure prescription and dispensing of drugs (e.g., systematic search for dihydropyrimidine déshydrogenase (DPD) deficiency by determination of uracil plasma concentration [uracilemia] prior to any prescription of fluoropyrimidine chemotherapy).

Since 2019, 30 DDSS have been referenced by HAS [13].

1.4 Tools for appropriateness of health technologies: supervising the practice of diagnostic/therapeutic procedures, or the prescription/use of health products

In addition to informing healthcare professionals to improve their practices and the appropriateness of care, it may be useful for the Ministry of Health to impose stricter controls on practices when a risk to public health has been identified (including a significant risk of inappropriate use) or when there is a risk of unjustified expenditure.

In this context, the use of MDs and medicines, and the practice of diagnostic or therapeutic acts, procedures, techniques and methods may be restricted to certain hospitals for a specific (renewable) period [14]. The list of these hospitals is given directly by the Ministry of Health or at a regional level by each regional health agency (*Agence Régionale de Santé,* ARS), in accordance with criteria established by the Ministry of Health after consulting the HAS.

This framework, issued by the Minister of Health after receiving the opinion of the HAS, can be proposed in the case of a safety signal for a health technology that is already reimbursed. However, it is more often proposed following a HTA carried out by the HAS, when a serious risk to patients is identified [15] (e.g., Essure, suburethral strips), or to allow the controlled dissemination of an innovative health technology by verifying that the proposed organisation is appropriate for the access to this innovative health technology (TAVI, fenestrated aortic stents).

This framework is based on the obligation of hospitals to comply with rules related to:

- the qualifications and training of professionals who may prescribe, perform, use or implement them;
- the technical conditions under which they are achieved;
- appropriate practice.

To date, around twenty health technologies have been regulated under article L1151−1 of the Public Health Code. These technologies can be medicinal products (CAR-T cells, gene therapies, etc.), therapeutic procedures (Langerhans islet transplants, mucosal dissection, etc.) or, more often, implantable MDs and their associated procedures (Transcatheter Aortic Valve Implantation. . .).

2. HTA and clinical practice guidelines (CPG): synergy and required consistency for appropriateness

2.1. HTA and CPG: different primary objectives but similar methods

As mentioned above, HTAs have been clearly defined by the INAHTA network (see Chapter 1). Clinical Practices Guidelines (CPG) are defined in the field of healthcare as « methodically developed proposals to help the practitioner and the patient to seek the most appropriate care in given clinical circumstances » [16]. CPGs are rigorous summaries of medical practice and evidence at a given time and are drawn up in accordance with the principles of Evidence-Based Medicine (EBM), defined in the 1990s [17].

The main difference between HTA and CPG is their primary objective. In the case of HTA, the aim is to provide the decision-maker (in this case the payer) with robust information on the appropriateness of reimbursing or delisting a health technology, from a population perspective and with a focused scope compared with CPGs (one or multiple health technologies vs. one or multiple indications/diseases). HTA is therefore a preparatory work for public decision-making [18]; the primary target of HTA is therefore the decision-maker. However, as HTA incorporates the current state of practice, it is also aimed at healthcare professionals and patients in the second instance. On the other hand, CPGs are aimed directly at healthcare professionals and patients, as their main objective is to help them identify the most appropriate care from an individual perspective ('the appropriate care for the appropriate patient at the appropriate time'). CPGs often have a wider scope than HTA reports and therefore are publications that can be used directly by healthcare professionals and patients.

This major difference has a direct impact on the level of involvement of experts (health professionals or patients) in the preparation of HTAs or CPGs. Thus, during an HTA process, the role of the external experts, speaking in their individual capacity, is consultative. The aim is to provide additional information and scientific advice, based on their experience, to that obtained through a systematic and critical analysis of the literature. In this way, the conclusions of the HTA consider both the analysis of published evidence and the experience of experts. Alternatively, the experts involved in the development of a CPG take an active part in the drafting of the recommendation, commenting on the arguments presented by the project leader(s), guideline methodologists, lead guideline developers and preparing in the drafting of the recommendations, which can be evaluated based on the drafted document.

Thus, although HTA and CPG may have different main objectives and sometimes different audiences (public and institutional decision-makers, health professionals, patients and health care users), they both rely on the critical analysis of available data and the opinion/experience of experts (professionals or health care users). In fact, their production and methodology are both derived from EBM as it was defined in the 1990s [17] and follow the same principles and values.

In addition to these intrinsic similarities in their development, there are several challenges to an integrated approach between the clinical recommendations resulting from CPGs and coverage decisions resulting from HTA assessments: in particular, ensuring consistency, saving time (eliminating duplication between HTA and CPG on the same topic), and optimizing the resources required to develop these products and the tools of implementation.

Ensuring consistency is a major challenge. Hogervorst et al. [19] conducted a systematic review to assess the similarities and differences between HTA reports and CPGs produced by the same country for multiple sclerosis drugs at the international level. Between 1995 and 2020, 132 HTA reports (70 initial assessments, 51 re-evaluations, 13 extensions of indications), including 46 from the HAS, and 9 CPGs, including one from the HAS, were identified: 6% of the final

recommendations in HTA reports and CPGs were contradictory, while in most cases they were concordant. However, there were differences in the populations per indication (differences related to different diagnostic criteria) and in the lines of treatment (concordant recommendations in only 45% of cases). In addition, 55 out of 132 HTA reports were based on CPGs (from different countries in more than half of the cases) and 7 out of 9 CPGs referred to HTA reports (from their own country). The risk of inconsistency between HTA and CPG was particularly linked to the fact that sometimes CPGs were not updated. The authors of the systematic review emphasized the need to strengthen communication between HTA and CPG producers at the different stages of the development process, to share/use the literature reviews carried out, to coordinate production schedules whenever possible and to consider/adopt the recommendations made in the respective reports. However, they noted the difficulty of integrating these two types of production when there are differences in the context of productions from different countries. At the HAS, several methods of interaction/integration between CPG and HTA have been introduced.

2.2. Simultaneous HTA and CPG development

Since 2022, the HAS implemented a procedure that facilitates the joint and simultaneous production of a CPG and an HTA by the HAS department of Good Practice Recommendations (*Service des Bonnes Pratiques,* SBP) and assessment of diagnostic and therapeutic procedures (*Service Evaluation des Actes Professionnels,* SEAP). This involves pooling both data and project leaders during the development phase, particularly for the critical analysis of literature. Several projects have been or are in progress, including the management of adult dysthyroidism, the management of patients exposed to chlordecone and dental implant procedures.

For example, the assessment of dental implant procedures for reimbursement raised the issue of antibiotic prophylaxis, which is a major public health concern and the source of much of the work of HAS on antimicrobial resistance. Thus, the need to address this HTA in parallel with guidelines on oral and dental management of patients at high risk of infective endocarditis was highlighted. A collaboration was therefore established between the two departments, SEAP and SBP, with several objectives.

Firstly, the SEAP supported the SBP on technical issues (in-house expertise: definition of oral and dental procedures, vocabulary, etc.) and helped to speed up the identification of the healthcare stakeholders to be involved to distinguish the various specialties, disciplines and initial training courses, as well as the professional and user bodies to be contacted to carry out the assessments. The SEAP also participated in the CPG working group meetings and in the review of the draft versions of the various documents (rationale and summary of recommendations to ensure consistency between SBP and SEAP projects, as some areas of evaluation are common). A similar approach has been developed since 2023 between the digital health department and SBP regarding digital health care technologies.

Overall, several aspects of this internal network have been implemented:

- Support and in-house expertise in a given field, at all stages of the evaluation (framework, technical and administrative aspects, definition of specialties, professional societies, etc.);
- Carrying out complementary work on related topics, with analysis of the common literature on a specific issue, with additional advice from the CPG working group, saving time on the recommendation and thus improving efficiency.
- Interdisciplinary involvement in current issues of major public health importance (e.g., antimicrobial resistance).

2.3. From HTA to CPG: a way to update CPG

CPGs are rigorous summaries of the practices and evidence at a given time, but there are many reasons why they should be kept up to date [17]. Obsolescence of CPGs can lead to practice that is no longer relevant or misuse of a practice, as well as a loss of confidence in the recommendations made. Conversely, the acquisition of new data may support an innovative practice and enable it to be disseminated more widely.

Among the various criteria for updating CPGs, several are related to HTA:

- Publication of data that changes the risk-benefit balance of existing interventions.
- Publication of results that are considered important or that measure the effects of an intervention using relevant new evaluation criteria;
- Availability of new preventive, diagnostic or therapeutic interventions;
- Changes in the value placed on scientific findings in a new demographic, social, cultural or political context;
- Publication of practice data showing that the current practice of the recommendations has become either optimal or, on the contrary, non-optimal/not used;
- Changes in the availability or accessibility of healthcare resources.
- etc.

The CPG update process involves three different steps [20,21]:

- Identification of new relevant data, including HTA;
- Assessment of the impact of this new data on current recommendations to determine if an update is needed;
- If necessary, update the recommendations using traditional or specific, full, partial or agile development methods.

The HAS adopted a proactive approach to updating its recommendations based, among other things, on the HTAs produced internally [22], and has set up an organization to achieve these objectives, including a dedicated unit that interacts between the different HAS departments (HTA, CPG) and with all its partners.

Pragmatically, any new HTA that could lead to a major change in existing recommendations is reported to the Recommendations Update Unit, which assesses the need and urgency for updating the good practice recommendations. This information can also be accessed via an email contact box (actualisation.recommandations@has-sante.fr): a data entry form is available for healthcare professional societies, health system user associations and other professional bodies wishing to report on a need to update a recommendation. The analysis of these alerts will enable priority updates to be included in the HAS work program.

For example, as mentioned above, antibiotic prophylaxis was addressed in the HTA report on dental implantology prior to the update of the CPG on antibiotic therapy in oral care practice. If the conclusions on the issue of antibiotic prophylaxis have been reached in the initial HTA, then this issue will be addressed in the update of the CPG, considering the analysis of the literature conducted during the HTA with a possible update. It will then be discussed again in the meeting with the guideline Working Group.

2.4. From CPG to HTA: a way to increase CPG implementation through reimbursement

The development of CPGs can highlight healthcare technologies that are recommended for use as part of best practice but are not yet reimbursed. In such cases, the HAS can take matters into its own

hands and conduct the necessary HTAs to provide an opinion on the medical value of these technologies for reimbursement. This was the case, for example, with the recommendations on the diagnosis of *Helicobacter pylori* infection published by the HAS in 2017 [23]; the lack of reimbursement/nomenclature listing for the labelled urea breath test, fecal antigen test (for the initial diagnosis of infection) and PCR (to search for the bacterium and a clarithromycin resistance mutation) had not allowed these tests to be included in the diagnostic strategy. These tests were the subject of an HTA in 2019, which should lead to updated recommendations soon.

Another example of synergy is the treatment of patients with Type 2 Diabetes Mellitus (T2DM), which has evolved rapidly in recent years. The expansion of indications for certain classes of drugs (gliflozines, GLP1 analogues, etc.) and the emergence of new evidence-based data (network meta-analyses, Australian Living Guidelines for T2DM) have led to a series of HTA assessments in 2021 and their integration into the new recommendations published in June 2024.

In addition, the existence of national and international CPG can be integrated into accelerated assessment methods. For example, within the framework of its HTAs, for diagnostic/therapeutic procedures, the HAS integrates French or foreign recommendations of CPGs, mainly to identify the overall management strategy in which the assessment to be carried out should be integrated [24]. A rapid assessment framework for diagnostic/therapeutic procedures also opens the possibility of limiting the analysis of the literature to systematic reviews (with or without meta-analysis), HTA reports and French or European CPGs. However, it is important that the CPG are independent, based on valid data with a high certainty of evidence and presenting graded and well-argued recommendations, and justifying the value of the medical procedure to be evaluated and its place in the management strategy [25].

3. HTA and CPG: the same implementation challenge for appropriateness

Beyond the production of HTA, we need to consider its impact on its target audiences, decision makers, health professionals and/or patients/users of health care services. This is an important strategic issue shared by the assessors involved in HTA decisions and CPGs.

The aim is to anticipate and promote their implementation and to evaluate the current achievement of the process known as "implementation" or "impact" or "uptake".

Numerous studies and research projects have examined the obstacles and levers for the successful implementation of clinical recommendations or public decisions, which remains a complex and multifaceted process [26–30].

From 2019, the HAS set the objective of improving the impact of its publications for health, social and medico-social professionals. This was one of the objectives of the HAS strategic plan 2019–2024 [31], considering particularly the recent work of the former Committee on the Impact of Recommendations (CIR) and the resulting action program to facilitate the adoption of recommendations by professionals [32].

This major challenge raises several key questions:

- Are the conclusions of the assessment, in terms of benefit and added value, followed up by the payers and decision makers (UNCAM, French ministry of health)? In terms of reimbursement or not? If not, why not? What other domains were considered in the decision (this may be an economic criterion that is not assessed as part of the procedure's assessment)?
- Are the HTA decisions on indications or conditions for use of the health technology reflected in practice? In other words, is it appropriate for professionals to prescribe the medical procedure or use the drug/MD?
- Do these decisions/recommendations have a positive impact on patient care and outcomes?

Almost all the opinions of HAS on the Clinical Benefit and Clinical Added Value are followed up by the French NHI.

The conclusions of the HTA report may have led to changes in practice in some cases, but it has also shown the need for long-term support/dissemination/communication. The 2008 assessment on cranial X-rays is exemplary; it specified the indications and non-indications for cranial and/or facial mass radiography in adults and children, whether the injury was traumatic or not. The aim was to avoid unnecessary irradiation, particularly in children [33]. The decisions were followed by the NHI, which in 2010 restricted reimbursement for cranial X-rays to the indications listed in the HTA. This was accompanied by a major effort to inform and mobilize health professionals (particularly emergency physicians) on the issue and led to a reduction of almost 50% in prescriptions for cranial X-rays in just over 10 years (209,000 cranial and/or facial mass X-rays were reimbursed in the private sector in France in 2022, compared with 407,000 in 2006) [34].

Another example is given by vitamin D dosage, which shows the need for sustained and repeated communication and support to professionals to bring about changes in practice following HTA. Given the significant increase in the number of 25(OH)D dosages (number of procedures multiplied by 10 between 2005 and 2012), the HAS was asked by the UNCAM to clarify the indications/non-indications for this test. In its 2013 HTA, the HAS considered that it was useful only in five indications: diagnosis of rickets and osteomalacia, mentions in the marketing authorizations of osteoporosis drugs, elderly people who suffer repeated fractures, outpatient monitoring of adult renal transplant recipients beyond 3 months after transplantation, surgical treatment of obesity in adults [35]. This opinion was included in the dedicated reimbursement list in 2014, and the UNCAM launched a communication campaign aimed at general practitioners, who are the main prescribers of this procedure (60% of prescribers). After a dramatic fall of >58% between 2013 and 2015, the number of tests raised again in 2015, with an increase of 76% between 2015 and 2022, particularly since 2019. However, according to an analysis carried out by the UNCAM, in 2022, only 9% of vitamin D tests reimbursed for patients aged between 16 and 65 years will correspond to an indication implemented by the HAS. In 2024, the UNCAM planned to repeat a campaign to remind general practitioners and biologists of the indications for prescribing vitamin D tests [36].

It should be noted that one possible way of measuring the impact of a CPG on healthcare professional practices is to analyze data from the French National Health Data System (*Système National du Système de Santé*, SNDS). This will be the case, for example, in the project to analyze SNDS data on antibiotic prescribing in oral practice. With a view to updating the 2011 recommendations from the French Medicines Agency on antibiotic prescription in oral care, the HAS was asked to draw up new recommendations. To measure the future impact of these recommendations once they have been published, an analysis of SNDS data was proposed. Certain oral procedures or pathologies, where antibiotic prescription is not recommended, will be targeted (dental avulsion, tooth devitalization, etc.).

A query comprising, for a given series of patients, the codification of a new medical procedure and an antibiotic prescription (within a short period of time), will be carried out before publication of the CPG and then after its publication over several years (short and medium term). In this way, it will be possible to assess the extent to which the recommendations have been followed and appropriated by healthcare professionals. This approach was used in two recent works from the HAS on magnetic resonance imaging (MRI) of lower limb [37] and preoperative care pathways of acromioplasty-treated patients older than 40 years in 2022 [38].

As far as the impact on patients is concerned, the reimbursement or coverage of healthcare technologies improves their accessibility. In addition, at the end of an HTA, the HAS may recommend that real-life studies are set up to measure the use, efficacy or tolerance of health technologies in everyday practice, outside the conditions of a clinical trial [39]. Nevertheless, patient acceptance of new health technology requires above all fair, clear and appropriate information to support shared decision-making. For example, in 2023, the HAS published a document to support shared decision-making on the options available after a mastectomy (breast reconstruction or flat chest) [40].

This question of the impact of HTA is a universal issue. In a systematic review carried out for INAHTA, Hailey et al. [41] looked at the impact of HTAs on decisions, and the methods used to measure it worldwide. A total of 51 studies were selected from 19 countries, including France: of the 142 decisions informed by HTA, the most frequent concerned clinical practice (67%), reimbursement (63%) or program funding (e.g., screening program) (37%). The influence of HTA on decisions varied according to the nature of the health technologies evaluated: evaluations of medicinal products had a major influence on reimbursement decisions.

Assessments of MDs and diagnostic/therapeutic procedures have led to decisions on reimbursement and professionals' clinical practice. Assessment of screening has helped public decision-makers to design and implement national screening programs. Mention was also made of the influence of evaluations on funding decisions made at hospital level. In contrast, few publications assessed the contribution of HTA to changes in patient outcomes or the effects on long-term clinical practice.

While iterative communication is necessary to better inform doctors, it is not enough to improve professional practices.

It is important to anticipate and establish an implementation strategy specific to each field. Anticipating the obstacles and levers specific to the area of CPG or HTA is most often an initial step in each implementation program. Thus, identifying the obstacles and levers in the HTAs for implementing the opinions they contain, for both decision-makers and professionals, is relevant. Numerous clinical and research studies on the obstacles and levers to successful implementation have shown that the implementation process, whatever the field, remains complex, and that the most favorable strategies must be multifaceted [28,30].

In a recent systematic review [30] of nearly 118 implementation studies on a portfolio of 16 clinical subjects, it was reported that 21% of studies referred to known theories or frameworks (theoretical domains framework-, social cognitive theory-), 50% sought to identify barriers to implementation in advance (literature review, questionnaire and interviews with stakeholders including healthcare professionals, etc.) and 36% involved stakeholders in the selection or adaptation of implementation interventions.

While the most common implementation strategies were training professionals in the recommendations (44%) and information systems/technology (41%), most studies used multifaceted interventions (75%). In all, 97 studies (82%) had an impact (improvement in one or more reported outcomes), with no single common rule of thumb.

Regardless of the implementation strategy defined, they all report that it is extremely important to involve healthcare professionals and stakeholders in improving practices, both upstream and downstream of the CPG development stages.

The case of scheduled caesarean sections is exemplary in this respect (see Box 1). It represents a genuine program for improving practices, including an assessment of the evidence and a definition of the indications for scheduled caesarean sections, updated recommendations for healthcare professionals, an information document for pregnant women, and a guide for analyzing and improving practices, with a host of tools to facilitate the improvement process, depending on the indications and situations chosen by those involved in the field.

This program has the support of all professional, associative and institutional players. In the private sector, a reduction of almost 28% in the number of scheduled caesarean sections between 2015 and 2022 has been observed, at a cost saving of 1.3 million euros [34], which could lead to the hypothesis of patients being referred to levels that are in line with the indications for a possible scheduled caesarean section.

Textbox 1. **Program to improve scheduled caesarean section practices at term**

In 2011–2012, given the heterogeneity of practices across the country concerning the use of caesarean sections (annual rates varying from 2% to 20%) [42,43], not explained by demographic or health indicators, the HAS embarked on a comprehensive program between 2012–2014 to improve practices for scheduled caesarean sections at term (after 39 WA).

The increased risk of morbidity associated with this practice, compared with a successful vaginal delivery attempt, as well as its higher financial cost, have led to question about the appropriateness of performing caesarean sections that are not medically necessary. Even if the ideal number of scheduled caesareans at term is unknown, it is important to reduce the disparity of practices between teams.

This program had several consecutive and coordinated components/actions:

- Assessment of the evidence on the multiple indications for caesarean sections led to the updating and development of CPGs for each of the indications for scheduled caesarean section at term [44]. These were supplemented by an information document for pregnant women [45], a guide to analyzing and improving practices [46], and a set of support materials (risk factor pathways, clinical pathways, information sheets, etc.) to facilitate quality procedures and enable healthcare professionals to take ownership of the tools and items they had chosen to work on at local level.
- A pilot phase of experimentation was carried out between 2013–2014, in partnership with all the players in the field: professionals, obstetricians, midwives, quality experts, pediatricians; women represented by the *Césarine* association, perinatal networks and certain regional evaluation structures, the General Directorate for Healthcare provision (DGOS) and the Regional Health Agencies (*Agence Régionale de Santé,* ARS).

On this basis, obstetrics teams were invited to implement a program to optimize the relevance of care, based on an analysis of their own practice to identify a concrete quality objective (desired practice). 165 volunteer teams, i.e., a third of all maternity units, signed up on a voluntary basis, representing 32% of the 507 maternity units, while still being representative of all French maternity units in terms of type and status. The feedback reports [47] produced at the end of 2014 describe the approaches and share the tools used. They include testimonials on the success factors and difficulties encountered in running the project and implementing the CPG.

This experiment was remarkable for several reasons:

- the extent of the commitment of the regions and hospitals;
- the implementation of a multifaceted program providing maternity teams, their correspondents and women with information documents and guides, methodological support and broad project management assistance, enabling them to select priority quality improvement points.

The feedback provided several lessons on the levers for successful implementation:

• The relevance of an active, motivated partnership between the various players (institutions, HAS, perinatal networks, healthcare professionals, user associations);

• The importance of taking the time to get together with all those involved in pregnancy monitoring (from different professions and different modes of practice) to define an initial quality objective, based on a valid/updated recommendation; taking part in this process of reflection is an essential lever for changing one's practice;

• The initial decision is taken collectively on practice improvement goals.

In terms of programmed caesarean sections rates, data from the private sector reveal a reduction in programmed caesarean section between 2015 and 2022 of almost 28% [34], i.e., 5153 fewer procedures, at a cost savings of over one million euros (1345,198 euros). This could lead to the hypothesis that patients will be referred to levels that are appropriate for their indications for a programmed caesarean section.

The number of stays with a scheduled caesarean section in the hospital sector varies slightly (35,477 stays with a scheduled caesarean section in 2022, versus 35,093 in 2015, according to Technical Agency for Information on Hospital Care (*Agence Technique de l'Information sur l'Hospitalisation,* ATIH) (data from public and private hospitals participating to the public service (*Etablissements Privés participant au Service Public,* PSPH)) [48]. This means that the French territory will not experience the international increase in numbers, unlike other Western countries [49].

As underlined, implementation of its productions is a major challenge for HAS and will be again one of the main objectives of the new HAS 2025 strategic plan. This includes identifying the needs/expectations of professionals and patients and the determinants of professional practices when scoping the project, testing the suitability of recommendations for professionals during the development process, improving the format and readability of productions, working with those involved in initial and continuing medical training to ensure that the recommendations are taken into account in training content, promoting the integration of recommendations into the digital tools used by professionals, improving user information and measuring changes in practices, based in particular on analysis of SNDS data.

4. Discussion

As a national scientific agency, the HAS faces several challenges in its HTA activities and those of the CPG. Decision-makers and health professionals demand up-to-date, rapid and trustworthy recommendations to ensure guidance in health decisions. The globalized health ecosystem is constantly changing (real world data, big data, personalized medicine, innovative digital and artificial intelligence applications). There are also recurrent time constraints and limited financial resources.

The COVID-19 pandemic has also accelerated data sharing, adoption of new methodologies and intensification of exchanges between health actors at national and international levels. It has led HAS to develop living guidelines in close collaboration with professional societies. Following this period, the HAS chosen to continue its approach of intensifying exchanges with other organizations in the health field, such as the Guidelines International Network, WHO, etc. The European Union Regulation on Health Technology Assessment will significantly advance collaboration and coordination of HTA processes across European Union Member States. HAS will continue to stand for anticipating and accompanying the substantial digital changes and great challenges that scientific agencies will face in the coming years with the applications of artificial intelligence through its HTA and guidelines activities.

Another way to produce rapid and trustworthy recommendations is the process of labelling guidelines from national professional societies by HAS, through methodological support and quality control, particularly regarding the selection of experts and conflict of interest issues as well as the systematic critical review of the literature. Thus, HAS represents the trusted third neutral party (without any interest) guaranteeing the methodological quality of the CPG.

Noteworthy, involvement of national professional societies is essential in both HTA and CPG productions by HAS, as they can act as expert providers or stakeholders providing the official position of the society on HTA or CPG conclusions. In both cases, the involvement of professional societies in HAS productions is multidisciplinary to collect the collegiate positions from all relevant stakeholders. Thus, the relationship between HAS and professional societies is bidirectional: HAS need national professional societies during the development of its productions, while some professional societies may need HAS for the development of their CPG.

5. Conclusion

In conclusion, beyond its primary role in informing reimbursement decisions, HTA plays a major role in the relevance of healthcare technologies (drugs, DM, diagnostic/therapeutic procedures). HTA is one of the foundations on which the development of information tools (proper use sheets, DDSS, etc.) for healthcare professionals on the proper use of healthcare technologies is based. HTA also provides a framework for the use of healthcare technologies to prevent their uncontrolled dissemination or inappropriate use, which can entail risks for patients. Furthermore, HTA and CPGs can be perfectly articulated to enable synergistic synchronic or asynchronic action to improve the relevance of care by enabling more dynamic and efficient actions, particularly in terms of robustness and updating. However, HTA shares with CPGs the same challenge of implementation in the field, which require, whatever the implementation strategy defined, a multifaceted approach involving iterative communication and the involvement of healthcare professionals, patients and stakeholders in improving practices, both upstream and downstream of the HTA stages.

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Sophie Blanchard: Writing – review & editing, Writing – original draft, Conceptualization. **Valérie Lindecker-Cournil:** Writing – review & editing, Writing – original draft, Conceptualization. **Bertrand Mussetta:** Writing – review & editing, Writing – original draft, Conceptualization. **Fréderic Nahmias:** Writing – review & editing, Writing – original draft, Conceptualization. **Cédric Carbonneil:** Writing – review & editing, Writing – original draft, Validation, Supervision, Project administration, Conceptualization.

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