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FROM CLINICAL RECOMMENDATIONS TO MANDATORY PRACTICE

The Introduction of Regulatory Practice Guidelines in the French Healthcare System

Pierre Durieux
Faculté de Médecine Broussais – Hôtel Dieu, Paris

Carine Chaix-Couturier
Isabelle Durand-Zaleski
Hôpital Henri Mondor, Créteil

Philippe Ravaud
Hôpital Bichat, Paris

Abstract

In an effort to control ambulatory care costs, regulatory practice guidelines (*références médicales opposables* or RMOs) were introduced by law in France in 1993. RMOs are short sentences, negatively formulated ("it is inappropriate to . . ."), covering medical and surgical topics, diagnosis, and treatment. Since their introduction, physicians who do not comply with RMOs can be fined. The fine is determined by a weighted combination of indices of harm, cost, and the number of violations.

The impact of the RMO policy on physician practice has been questioned, but so far few evaluations had been performed. At the end of 1997, only 121 physicians had been fined (0.1% of French private physicians). The difficulty of controlling physicians, the large number of RMOs, and the lack of a relevant information system limit the credibility of this policy.

The simultaneous development of a clinical guideline program to improve the quality of care and of a program to control medical practice can lead to a misunderstanding among clinicians and health policy makers. Financial incentives or disincentives could be used to change physician behavior, in addition to other measures such as education and organizational changes, if they are simple, well explained, and do not raise any ethical conflict. But these measures are dependent on the structure and financing of the healthcare system and on the socioeconomic and cultural context. More research is needed to assess the impact of interventions using financial incentives and disincentives on physician behavior.

Keywords: Physician's practice patterns, Health policy, Practice guidelines, Physician incentive plans

Over the past two decades, clinical guidelines have become an industry in most developed countries (20). National bodies for clinical guidelines elaboration were set up in many countries following a report published by the Institute of Medicine in the United States (17). In France a national quality assurance agency was established in 1990 by the Ministry

of Health, and it developed a clinical guideline program. This agency, *Agence Nationale pour le Développement de l'Evaluation Médicale* (ANDEM), was replaced in 1996 by *Agence nationale d'accréditation et d'évaluation en santé* (ANAES). During the same period, clinical guidelines played a major role in French government policy for the ambulatory sector. In efforts to control ambulatory care costs and to change clinical behavior, regulatory practice guidelines were imposed by law.

The use of clinical guidelines to control healthcare costs, combined with a system of fines for doctors who do not comply, raises questions about the impact of this policy on costs, quality of care, and physician behavior. This article describes the policy introduced in France in 1993 and its potential implications for the development and implementation of clinical guidelines.

THE DEVELOPMENT OF CLINICAL GUIDELINES IN FRANCE

More than 20 French medical societies have organized over 100 consensus conferences during the last decade, largely promoted by ANAES (1;3). In 1992, at the time when consensus conference programs were subject to many criticisms in the world, ANAES began to formalize a clinical guidelines program (2;26), based on the Agency for Health Care Policy and Research (AHCPR) experience. Other guideline programs were also implemented by the public hospital network for the Paris area (*Assistance Publique-Hôpitaux de Paris*) (10) and by the national network of cancer hospitals (*Fédération nationale des centres de lutte contre le cancer*) (12;25). Most efforts of the French guideline program were devoted to clinical guideline elaboration rather than to clinical guideline implementation. However, the development of a clinical guideline and consensus conference program in France, the active collaboration between the national agency ANAES and major scientific societies, and the participation of well-recognized experts in this collaboration played an important role in the implementation of the concept of evidence-based medicine in France. Most French physicians now accept the development of clinical guidelines; they are aware of the current scientific and economic context and of their responsibilities in this area.

CLINICAL GUIDELINES AND CONTROL OF HEALTHCARE COSTS

Implementation of Regulatory Practice Guidelines

France is challenged by an increase in healthcare expenditures. Healthcare spending as a percent of gross domestic product grew from 8.5% to 9.7% from 1985 to 1997, a rate higher than in most European countries. This increase was particularly large for ambulatory care, and public authorities negotiated a program to control ambulatory care costs with the national health insurance system and medical unions.

Regulatory practice guidelines, known as *références médicales opposables* (RMOs) were introduced by law in France in 1993 (8). RMOs are defined as "recognized scientific criteria that make it possible to define inappropriate care and prescriptions, and the frequency with which such care or prescriptions are used by the patient" (9). RMOs cover medical and surgical topics as well as diagnosis and treatment procedures (for example, prescription of antibiotics, thyroid function tests, hysterectomy, colonoscopy, and diagnosis of viral hepatitis). RMO topics and RMOs are selected by representatives of French insurance funds and doctors' unions. The criteria for selecting topics are not clear but include high cost, high risk, high prevalence of the disease, and high (supposed) variations in practice. For each of these topics, from 1 to 10 RMOs are selected from specific guidelines drawn up by ANAES and the French Drug Agency (9).

Table 1. Examples of RMOs

RMO	Index of harm	Index of cost
It is inappropriate to systematically determine the carcinoembryonic antigen level in colorectal cancer screening.	0.5	1.25
It is inappropriate to perform esophageal pH monitoring in infants with clinically evident, even complicated, gastroesophageal reflux, except in case of malaise.	0.5	1.25
It is inappropriate to perform glycosylated hemoglobin measurement in non–insulin-dependent diabetes screening.	0.5	1.25
It is inappropriate to perform a CT scan or an MRI in the diagnosis or the surveillance of osteoarthritis of the spine, except when a complication or another disease is suspected by routine tests or radiographic features.	0.5	1.5
It is inappropriate to prescribe exercise therapy for patients with acute low back pain.	0.5	1.25
It is inappropriate, due to the risk of hemorrhage, to prescribe a nonsteroidal anti-inflammatory drug to patients who are treated with oral anticoagulants, heparin, or ticlopidine.	1.5	1.0
It is inappropriate to treat systemic hypertension before having measured blood pressure three times over a 2-month period.	1.0	1.5
It is inappropriate to prescribe injectable anti-ulcer therapy when it is possible to give treatment orally.	0.5	1.25

RMOs are clearly stated, short, prescriptive recommendations that are negatively phrased ("It is inappropriate to . . ."") (Table 1). A list of applicable RMOs is published by the government every year in the *Journal Officiel de la République Française*. Each year this list is revised, new RMOs concerning new topics appear, and some RMOs are withdrawn. In 1998 a total of 165 RMOs concerning 43 topics were published for general practitioners; 20 other topics concerned only specialists working in private practice. In addition to annual publication in the *Journal Officiel de la République Française*, RMOs are mailed by the major national health insurance fund (*Caisse nationale d'assurance maladie des travailleurs salariés*) to the 110,000 French physicians working in private practice. They are also widely published and discussed in French professional medical journals.

Since the introduction of these regulatory guidelines, physicians (general practitioners and specialists) who do not comply with RMOs can be fined. Each year the national health insurance funds inspect a certain number of randomly chosen private practitioners. The inspection consists of reviewing a 2-month period of prescriptions by the physician; it is carried out by physicians who belong to the medical department of the national health insurance. All prescriptions for a clinical situation that is addressed by an RMO are collected. Then each prescription is checked against the corresponding RMO. If this inspection shows that the physician did not comply with some RMOs, a report is sent to a local committee of representatives of health insurance funds and medical unions, and the physician can be penalized by this committee. The fine is determined by a weighted combination of an index of the RMO's harm, an index of its cost, and the number of violations (8). An index of harm (1.5, 1.0, or 0.5) is assigned to each RMO. The number of violations in a 2-month period must not exceed 1 for an RMO that has an index of 1.5, 3 for an RMO that has an index of 1, and 6 for an RMO that has an index of 0.5. Similarly, an index of cost (1 for inexpensive procedures; 1.25 for expensive procedures; 1.50 for very expensive procedures) takes into account the increased expense (Table 1). RMOs do not apply to hospital practice. Hospital costs are controlled through an annual global budget that was implemented in 1983.

Nevertheless, new budget restraints and the 1996 reform, named the Juppé reform, had a notable impact on the implementation of policies controlling practices of all physicians, whether they work in private practice or in hospitals (3). An accreditation procedure under the responsibility of ANAES is mandatory for all public and private hospitals. New regional authorities are in charge of management and strategic planning for both public and private hospitals in a given region. These regional authorities are also in charge of ensuring equal access to care and quality of care and are able to restructure the supply of hospital care within each region. Quality of care is therefore used as a criterion in the negotiation of hospital budgets. The Juppé reform recommended the development of clinical guideline programs in hospitals, including *références médicales* similar to those developed in the ambulatory care sector (3).

Impact of Regulatory Practice Guidelines on Physician Behavior

Some early studies showed that the RMO policy had some impact on costs. One year after its implementation, the savings on drug expenditures was estimated to be approximately US $6 million (18). However, the impact in 1994 of the RMO policy on drug expenditures was not observed for therapeutic RMOs published after 1994 (19). A recent observational study showed that French physicians were unable to identify RMO topics and RMOs among a list of actual and fictitious items. In this study, average physicians' scores on a self-administered questionnaire were not different from the score that would have been obtained by chance (9).

The long-term results of financial disincentives on physicians' behavior depend on trust, legitimacy, and the quality of controls (21). Most health professionals worry that efforts to reduce the cost of healthcare services could decrease quality of care. They resent the financial penalties. In 1998, 60% of French physicians declared that the RMO policy could affect the quality of care (22). However, the real impact of the RMO policy on physician practice has be questioned, and so far few evaluations have been performed.

At the end of 1997, 26,682 physicians (23.6% of physicians working in private practice) had been inspected. Of these, 483 were considered for sanctions, and 121 were fined (0.1% of French private physicians) (4).

In the first years, audits were manual, which limited their number and effectiveness; it took 300 hours to check the prescriptions ordered by one doctor over a 2-month period (5). This difficulty limits the credibility of this policy, because the policy is not perceived by general practitioners as a real threat. The current computerization of medical records in physicians' offices and retail pharmacies could now make controls easier.

The RMO policy was questioned in 1997 when reform of the French health system changed the rules (3). According to this reform, French physicians working in private practice could also be collectively fined at the end of each year if they overspent the budget prescribed by the French parliament. On the other hand, they could receive a bonus if they did not overspend their budgets. Many physicians protested that this principle was unethical because a doctor should not be rewarded for prescribing less (6;7). This policy was also considered to be against the code of ethics set by the French Medical Association (*Conseil National de l'Ordre des Médecins*), which states that physicians are free to prescribe the best care they deem necessary (3). This reform created a major conflict among the French government, the social security, and medical unions that had a negative impact on the implementation of RMO policy.

The number of RMOs is probably too large, and the usefulness of some RMOs has also been questioned. A study on prescription of vasodilator agents for peripheral occlusive artery diseases showed that, 1 year before release of the RMO on this topic, 80% of prescriptions in a population of French general practitioners was appropriate (28).

ISSUES FOR DEBATE

The simultaneous development of a clinical guideline program to improve the quality of care and of regulations or laws enacted to control medical practice and contain costs can lead to misunderstanding among clinicians and health policy makers. Some clinicians do not accept clinical guidelines because they think that the guidelines' only objective is to decrease costs. Some health policy makers promote clinical guidelines for the same reason. However, practice guidelines may decrease, leave unchanged, or increase healthcare costs. When there is a decrease or no change in expenditures, guidelines represent a cost-minimizing strategy. Otherwise, economic analysis can be used to determine whether the increased cost is justified by increased quality.

The objectives of a clinical guideline program should be clearly stated before implementation. As an example, it has been shown that computers constitute the best way to implement clinical guidelines through reminders (13;14;16). The French Ministry of Health has recently proposed to private practitioners some incentives for installing computers in their offices. But many physicians have refused these incentives because of the risk of control of their practice.

Another aspect of interest when developing practice guidelines is the existing structure of the healthcare system, which may create incentives or disincentives to use guidelines. The French healthcare system is characterized both by real liberty for those involved (physicians and patients) and by strong governmental control (3). Introduction of mandatory guidelines such as RMOs at the national level is possible only in a centralized healthcare system, where the government plays the major role and medical unions have limited power.

In a fee-for-service and freedom-of-choice environment such as the one found in France, physicians are at financial risk if they deny a prescription on the grounds that it is contrary to the guidelines. It has been stressed that financial incentives and disincentives must not create a conflict of interest between physician revenue and the quality of care given to the patient (27). Some physicians try to maximize their revenue and set themselves a target income, and they will modify their behavior to reach the target. The general recommendation when implementing financial incentives in the healthcare system is to make them simple, transparent, and direct: there should be a binary relation between the incentive and the desired behavior from doctors or patients.

The difficulty in changing physician behavior does not involve only the motivation of physicians. Since physicians are subjected to growing pressure from their patients, whose demands are increasing along with generalized access to health care and media coverage of new medical procedures, patients must be informed and accept any new policy aiming at changing physician behavior.

An aspect of interest concerns differences in practices between countries and the applicability of scientific evidence. Regulatory practice guidelines such as RMOs should be applied nationally for all physicians working in private practice. Thus, they should be based on the best evidence and should not be subject to any controversy. The methodology of clinical guideline development is a mix of scientific evidence and expert opinion. Methodologies for appraising evidence and the strength of evidence are essential in guideline elaboration. It has also been shown that evidence-based recommendations are better followed by clinicians than recommendations not based on scientific evidence (15). Scientific evidence comes from controlled clinical trials. However, it is well known that what can be achieved in the controlled environment of a clinical trial may not be achieved when a technique is used in routine practice. Most of the literature published in major journals describes research at large medical centers in English-speaking countries. We do not know exactly how the results of these studies apply to other settings. For example, the frequency of deep venous thrombosis varies from country to country. How could the results of a study performed at a

major U.S. medical center apply in the environment of a small tertiary heathcare center in France? Prophylactic practices also differ from country to country; as an example, the use of low-molecular-weight heparin is common in France; but not in the United States. It has also been shown that there are cultural differences in practices between countries (23). These differences could be reflected in differences in guideline recommendations. Eisinger et al. (11) recently compared U.S. and French clinical recommendations for women at increased risk for breast and ovarian cancer. They observed that the two countries' guidelines differ in some areas of clinical uncertainty, e.g., breast self-examination (11). Practice data are rarely taken into account in the guideline elaboration process. In a study published in 1997, only 0.7% of Finnish guidelines initiated a survey of clinical practice before development (11). It has been proposed by ANAES researchers that practice data should be used to improve evidence-based guidelines (24). For these authors, it is important to analyze physicians' expectations, opinions, and practices concerning a specific subject in order to define the appropriate questions and adapt the content of the guidelines, particularly when scientific evidence is unclear. Such a procedure is also a way to include guideline-targeted physicians in the process of guideline elaboration, which is considered to be a criterion of successful implementation (13;14). For these reasons, it is probably impossible to impose a mandatory practice at a national level for all physicians.

Financial incentives and disincentives could be used in addition to other measures, such as education and organizational changes that aim at transforming clinical practice or patients' compliance. More research is needed to assess the impact of interventions using financial incentives and disincentives on physician behavior. Contrary to other interventions such as education or the use of reminders, the possibility of using financial incentives and disincentives and the type of incentives and disincentives used to change physician behavior depend directly on the structure and financing of the healthcare system and on its socioeconomic and cultural context. Thus, the experiments made in one country and the results obtained may not be reproduced straightforwardly in another country unless major structural reforms are undertaken.

Successful implementation of practice guidelines requires a good knowledge of structural and personal factors that may motivate the actors in the healthcare system to accept or refuse change. The presence of an environment and an attitude supporting cost containment may be the critical factor for securing cost-effective practice behavior among physicians. The French experience tends to support the idea that practice guidelines are not tools of cost containment. Factors promoting such an environment will include trust, accurate data, and supportive medical leadership at all organizational levels.

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