

# The Introduction of Regulatory Practice Guidelines in the French Health Care System

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Over the past two decades, following a report published by the Institute of Medicine in United States of America (17), clinical guidelines have become very popular in most developed countries (20). In France, over twenty French medical societies have organized consensus conferences, largely promoted by a French national Agency ANDEM (*Agence Nationale pour le Développement de l'Évaluation Médicale*). This Agency, set up in 1990 has been replaced in 1996 by ANAES (*Agence nationale d'accréditation et d'évaluation en santé*<sup>1</sup>) (1;3). In 1992, at the time when consensus conference programs were subject to many criticisms, ANDEM began to formalize a clinical guidelines program (2;23), based on Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality, AHRQ) experience. Other guideline programs were also developed by *Assistance Publique-Hôpitaux de Paris* (AP-HP), the public hospital network for the Paris area (9), by the national network of cancer hospitals (*Fédération nationale des centres de lutte contre le cancer*) (12) and by several medical societies.

During the same period, clinical guidelines played a major role in French government policy for the ambulatory sector. In an effort to control ambulatory care costs and change clinical behaviour, regulatory practice guidelines were imposed by the law. The use of clinical guidelines to control health care costs combined with a system of fines for doctors who do not comply raises some questions concerning the impact of this policy on costs, quality of care and physician behaviour. This article describes this policy introduced in France in 1993 and its potential implications on the development and implementation of clinical guidelines.

## THE IMPLEMENTATION OF REGULATORY PRACTICE GUIDELINES

In France health care spending as a percent of gross domestic product grew from 8.5 to 9.7% from 1985 to 1997. This increase was particularly important 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 « recognised 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 » (10). RMOs cover medical and surgical topics as well as diagnosis and treatment procedures (table 1). 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 of practice. For each of these topics, from 1 to 10 RMOs are selected from specific guidelines drawn up by ANAES and AFSSAPS, the French Drug Agency (10).

RMOs are clearly stated, short, prescriptive recommendations, negatively formulated ("It is inappropriate to...", see some examples in table 2). A list of applicable RMOs is published every year by the government 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 was published for general practitioners ; twenty others 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 (the *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 general practitioners (GPs) and specialists who do not comply to RMOs can be fined. Each year, the national health insurance funds inspect a certain number of private practitioners randomly chosen. The inspection consists in reviewing a two-month period of prescriptions of a physician, it is

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<sup>1</sup> See the internet site of ANAES: [www.anaes.fr](http://www.anaes.fr)

carried out by physicians who belong to the medical department of the national health insurance. All prescriptions concerning a clinical situation which is the topic of a RMO are collected. Then each prescription is checked against the corresponding RMO. If this inspection shows that the physician did not comply to some RMOs, a report is sent to a local committee of representatives of health insurance funds and medical unions and the physician can get penalties from this committee. The fine is determined by a weighted combination of indices of harm, and cost of each RMO and the number of violations (8). An indice of harm (1.5, 1 or 0.5) is assigned to each RMO. The number of violations on a two-month period should not exceed 1 for a RMO which has an indice of 1.5, 3 for a RMO which has an indice of 1 and 6 for a RMO which has an indice of 0.5. Similarly, an indice of cost (1 for non expensive procedures ; 1.25 for expensive procedures ; 1.50 for very expensive procedures) takes into account the level of increased expense (table 2). RMOs do not apply to hospital practice.

## **THE IMPACT OF REGULATORY PRACTICE GUIDELINES ON PHYSICIAN BEHAVIOUR**

Very few studies evaluating the impact of this policy have been performed. Some early studies showed that the RMO policy had some impact on costs. A study was conducted by CREDES, a French institute of research on health economics, funded by the national health insurance fund. This study looked at the impact of 10 RMOs introduced in 1994 and 8 RMOs introduced in 1995 and was based on data drawn from a sample of 2300 physicians recorded between 1992 and 1995. One year after implementation of RMOs, it was estimated that the saving on drug expenditures was approximately 6 millions dollars (18). However, the impact on drug expenditures of the RMO policy observed in 1994 was not observed for therapeutic RMOs published after 1994 (19).

To evaluate the level of awareness and knowledge of RMOs, we performed an observational study among 321 general practitioners. Participants were asked to identify RMO topics among a list of actual RMO topics and fictitious RMO topics and RMOs themselves among a list of actual RMOs and fictitious RMOs. The outcome measure was an average score out of 100 [95% confidence interval (CI)] on awareness of RMO topics and knowledge of RMOs. The average overall score was 55.8 out of 100 (95% CI, 53.3 -58.3) for RMO topics and 50.5 (95% CI, 48.3 -52.7) for RMOs themselves: 53.2 (95% CI, 51.1 -55.3) for diagnostic RMOs and 47.8 (95% CI, 45.6 -50.0) for therapeutic RMOs. Chance would have yielded an expected mean score of 50. When there were differences between average physicians' scores and 50, they were not very large and despite the fact that 80% of respondents declared that they sometimes consult RMOs, 44.3% at the time of patient consultation, this survey did not provide evidence of a strong effect of the implementation of RMO policy on awareness and knowledge of RMOs among physicians (10).

## **DISCUSSION**

The long term results of financial disincentives on physicians' behaviour depend on trust, legitimacy and the quality of controls (21). Several reasons could explain the failure of the RMO policy.

Firstly, Most health professionals worry that efforts to reduce the cost of health care services could decrease quality of care. They resent the financial penalties. In 1998, 60 percent of French physicians declared that the RMO policy could affect the quality of care (22).

Secondly, at the end of 1997, 26 682 physicians (23.6 percent of physicians working in private practice) have been inspected. 483 of them were considered for sanctions and among them, only 121 where fined (0.1 percent of French private physicians) (4). In the first years, checks used to be manual, which limited their number and effectiveness, it took 300

hours to check prescriptions ordered by one doctor over a two-month period (5). Thus, this difficulty limits the credibility of this policy, not perceived by GPs as a real threat.

Thirdly, the number of RMOs was probably too important and the usefulness of some RMOs had also been questioned. In a study on prescription of vasodilator agents in peripheral occlusive artery diseases, it has been shown that 80 percent of prescriptions of a population of French GPs surveyed was appropriate according to the RMO one year before its release (25).

Fourthly, the RMO policy was questioned in 1997 when the 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 contrary, 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 state that physicians are free to prescribe the best care they deem necessary (3). This reform raised an important conflict among the French government, the Social security and medical unions, which had a negative impact on the implementation of RMO policy. This conflict still persists despite a large meeting organized by the French government with medical unions in July 2001 (named *Grenelle de la santé*). Thus, at this time it impossible to know what will be the future of the RMO policy.

## **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 a misunderstanding among clinicians and health policy makers. The development of a clinical guideline and consensus conference program in France, the active collaboration between the national agency ANAES and majors scientific societies and the implication of well-recognized experts in this collaboration played an important role in the acceptance of clinical guidelines. Physicians are aware of the current scientific and economic context and of their responsibilities in this area. However, some clinicians do not accept clinical guidelines because they think that their only objective is to decrease costs.

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 to favor the implementation of computers in their offices. But many physicians 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 health care system which may create incentives or disincentives to use guidelines. The French health care system is characterized both by real liberty for those involved (physicians and patients) and by a strong governmental control (3). Only a centralized healthcare system where the government play the major role and medical unions have a limited power could introduce national mandatory guidelines such as RMOs (8).

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 or disincentives must not create a conflict of interest between physician revenue and the quality of care given to the patient (24).

## CONCLUSION

A successful implementation of practice guidelines requires a good knowledge of structural and personal factors that may motivate the actors of the healthcare system to accept or refuse change. The presence of an environment and attitude supporting cost containment may be the critical factor for securing cost-effective practice behaviour 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.

This paper is drawn from materials published in the following articles:

1. Durieux P, Gaillac B, Giraudeau B, Doumenc M, Ravaud P. Despite financial penalties, French physicians' knowledge of regulatory practice guidelines is poor. *Arch Fam Med* 2000;9:414-418
2. Chaix-Couturier C, Durand-Zaleski I, Jolly D, Durieux P. Effects of financial incentives on medical practice: results from a systematic review of the literature and methodological issues. *International Journal for Quality in Health Care* 2000;12:133-142
3. Durieux P, Chaix C, Durand Zaleski I, Ravaud P. From clinical recommendations to mandatory practice: the introduction of regulatory practice guidelines in the French health care system. *International Journal of Technology Assessment in Health Care* 2000;16:969-75

## REFERENCES

1. Agence nationale d'accréditation et d'évaluation en santé. Les conférences de consensus. Base méthodologique pour leur réalisation en France. Paris, ANAES, 1999.
2. Agence nationale d'accréditation et d'évaluation en santé. Les recommandations pour la pratique clinique. Base méthodologique pour leur réalisation en France. Paris, ANAES, 1999.
3. Colin C., Geffroy L., Maisonneuve H & al. Country profile. France. *The Lancet*, 1997, 349, 791-97.
4. Delorme J. La cour des comptes et les RMO. *Le Concours Médical*, 1999, 121:356-358.
5. Dixon J. France seeks to curb health costs by fining doctors. *British Medical Journal*, 1997, 315, 895-896.
6. Dorozynski A. French doctors agitated over cash « bonus ». *British Medical Journal*, 1998;316:1037.
7. Dorozynski A. France launches plan to control health costs. *British Medical Journal*, 1998;317:164.
8. Durand-Zaleski I., Colin C. & Blum-Boisgard C. An attempt to save money by using mandatory practice guidelines in France. *British Medical Journal*, 1997, 315, 943-946.
9. Durieux P. & Ravaud P. From clinical guidelines to quality assurance: the experience of Assistance Publique-Hôpitaux de Paris. *International Journal for Quality in Health Care*, 1997, 9, 215-219.
10. Durieux P, Gaillac B, Giraudeau B, Doumenc M & Ravaud P. Despite financial penalties, French Physicians' knowledge of regulatory practice guidelines is poor. *Archives of Family Medicine*, 2000, 9,414-418

11. Eisinger F., Geller G. & al. Cultural basis for differences between US and French clinical recommendations for women at increased risk of breast and ovarian cancer. *The Lancet*, 1999, 353, 919-920.
12. Fervers B., Bonichon F., Demard F. & al. Méthodologie de développement des standards, options et recommandations diagnostiques et thérapeutiques en cancérologie. *Bulletin du Cancer*, 1995, 82, 761-767.
13. Grimshaw J. & Russel I. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *The Lancet*, 1993, 342, 1317-1322.
14. Grimshaw J.M., Russel I.T. Achieving health gain through clinical guidelines. II: Ensuring guidelines change medical practice. *Quality in Health Care*, 1994, 3, 45-52.
15. Grol R., Dalhuijsen J., Thomas S. & al. Attributes of clinical guidelines that influence use of guidelines in general practice: observational study. *British Medical Journal*, 1998, 317, 858-861.
16. Hunt D.L., Haynes B., Hanna SE & al. Effects of computer-based clinical decision support systems on physician performance and patient outcomes. A systematic review. *Journal of the American Medical Association*, 1998, 280, 1339-1346.
17. Institute of Medicine, Committee to Advise the Public Health Service on Clinical Practice Guidelines. Clinical practice guidelines. Directions for a new program. Washington: National Academy Press, Field MJ, Lohr KN Eds 1990.
18. Le Fur P, Sermet C. Les références médicales opposables, impact sur la prescription pharmaceutique. Centre d'Etude et de Documentation en Economie de la Santé (CREDES), Paris 1996 (Biblio N° 1116).
19. Le Pape A. & Sermet C. Les références médicales opposables sur le médicament: bilan de trois années d'application. Centre d'Etude et de Documentation en Economie de la Santé (CREDES), Paris 1998 (Biblio N° 1237).
20. Miles A., Bentley P., Polychronis A. & al. Recent progress in health services research: on the need for evidence-based debate. *Journal of Evaluation in Clinical Practice*, 1998, 4, 257-265.
21. Monrad A. Incentives and financial methods. *Health Policy* 1995,34,205-220.
22. Ordre National des Médecins. Maîtrise des dépenses: les médecins en quête de repères. Bulletin de l'Ordre des Médecins, Mars 1998,10-17.
23. Roche N. & Durieux P. Clinical practice guidelines: from methodological to practical issues. *Intensive Care medicine*, 1994, 20, 593-601.
24. Rodwin M.A. Medicine, Money and Morals: physicians'conflicts of interest. Oxford University Press, Oxford, 1993.p 152-62.
25. Vuittenez F., Guignard E., Comte S. Evolution de la prescription des vaso-actifs périphériques et cérébraux avant et après les références médicales opposables. *La Presse Medicale* 1999, 28, 122-126.

**Table 1: List of Topics selected for regulatory practice guidelines (for general practitioners). Source: Journal Officiel de la République Française, 5 décembre 1998**

1. Prescription of non-steroidal anti-inflammatory drugs
2. Prescription of antibiotics
3. Diagnostic imaging of back pain
4. Hypnotic and tranquilizing drugs
5. Diagnosis of pregnancy using chorionic gonadotrophic hormone
6. Systematic blood and urine testing
7. Surveillance of oral contraception
8. Treatment of non-insulin dependent diabetes
9. Ultrasounds during pregnancy
10. Digestive endoscopy
11. Thyroid function tests
12. Treatment of hypertension
13. Treatment of hypercholesterolaemia
14. Magnesium blood and serum concentrations
15. Tumor markers
16. Preoperative routine examination
17. Treatment of gastric and duodenal ulcer
18. Vasoactive drugs in the treatment of arterial ischaemia
19. Hysterectomy
20. Knee exploration and surgery
21. Skin cancer
22. Acne
23. Prescription of neuroleptic drugs
24. Management of psychotic patients
25. Exploration of gastro-oesophageal reflux in neonates and children
26. Treatment of prostate benign adenoma
27. Treatment of prostate cancer
28. Medical treatment of cerebral ischiema
29. Treatment of venous insufficiency of the lower limbs
- 30 Antidepressant drugs
31. Lipid lowering treatment
32. Chronic venous insufficiency of the lower limbs: diagnosis and treatment
33. Sterility
34. Current diagnoses in hematology
35. Diagnosis of viral hepatitis
36. Long term oxygen therapy for chronic respiratory insufficiency
37. Physiotherapy
38. Colonoscopy
39. Dizziness in adults
40. Exploration of the Thyroid (function tests excluded)
41. Surgery of lower limb varicosities

**Table 2: examples of RMOs**

<b>RMO</b>	<b>Indice of harm</b>	<b>Indice of cost</b>
1. It is inappropriate to systematically determine the carcinoembryonic antigen level in colorectal cancer screening	0.5	1.25
2. 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
3. It is inappropriate to perform glycosylated hemoglobin measurement in non-insulin dependent diabetes screening	0.5	1.25
4. 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
5. It is inappropriate to prescribe exercise therapy in acute low-back pain patients	0.5	1.25
6. 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
7. It is inappropriate to treat systemic hypertension before having measured blood pressure 3 times over a two-month period.	1	1.5
8. It is inappropriate to prescribe injectable antiulcer therapy when it is possible to give per os treatment	0.5	1.25