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**Opinion n°104**

**The “Personal Medical Record”  
and computerisation of health-related data**

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## Introduction

On March 19, 2008, the French Minister for Health, Madame Roselyne Bachelot, referred to the National Consultative Ethics Committee (CCNE) for an opinion on the development of information technology in a medical context. The referral bore on the risk of loss of confidentiality of medical data in patient records due to electronic access to them by healthcare providers. It also requested the Committee's views on practical measures which could be taken to satisfy the need for access to the information by health carers while protecting the patient's right to retain control over its dissemination.

The Minister's referral also called for a more specific and in-depth study of the "*Dossier Médical Personnel*" (DMP) (Personal Medical Record) which emerged after prolonged reflection on the design of an electronic tool to improve coordination, quality and continuity of care. The nature of this tool has evolved over time. In particular, although it was originally intended as a tool for communication between practitioners caring for a specific patient, (a "shared medical record"), it became a "personal medical record" over which a patient must be able, at all times, to exercise control. Patient consent is required to create the DMP, to access it, and possibly to add to it. The patient is an actor in a system over which he retains right of access and the possibility of drawing a veil over biographic events and behaviours. As described in the law dated July 13, 2004<sup>1</sup>, the DMP aims to "*improve coordination, quality and continuity of healthcare, which are necessary ingredients for a satisfactory level of good health*" with systematic patient access "*to information needed to monitor healthcare and medical intervention. The personal medical record also includes a section specifically concerned with prevention*".

The DMP is a complex creation which combines:

- Specific measures provided by the July 13, 2004 law on Sickness Insurance (modified by a law dated January 30, 2007), not as yet defined by implementing decrees;
- Legislation from the *Code de la Santé Publique* regarding the confidentiality of health-related information (law dated March 4, 2002) and its implementing decrees;
- Legislation from by the *Code de la Santé Publique* concerning healthcare data hosts (law dated March 4, 2002 modified by the law dated January 30, 2007 and its implementing decrees);
- The measures in the law on "Security and Liberty", dated January 6, 1978, modified on several occasions.

Several administrative and technical bodies have already been consulted on whether this specific type of electronic medical record — which for the time being is still in the planning stage — should be implemented. Their opinions and reports have evidenced a degree of organisational complexity which had not been exhaustively addressed in the early design phase.

At this time, computerisation of the healthcare system, in hospitals in particular, does not seem to have reached the quantitative and qualitative level of excellence required for the

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<sup>1</sup> Article 161-36-1, Code of Social Security

DMP to be implemented. Furthermore, many uncertainties persist regarding the contents of the DMP. Some members of the medical community consider that it should only be a rather technical document (including medical test results, diagnoses, etc.) but omitting some of the major health-related components, in particular those concerning prevention. The length of time during which information would be recorded in the DMP, possibly varying with the nature of that information, remains to be defined. Summing up, various essential prerequisites for the DMP to be successful would seem to be missing, entirely or in part.

While the DMP's stated objective is to improve healthcare coordination, the authorities justifiably hope that better coordination would also have favourable economic consequences. Irrespective of the doubts that have been expressed on the DMP's possible economic impact were it to be implemented, it is clear that widespread support for the scheme by the public and by health carers would be essential for that impact to be favourable.

## **1/ Assessment of the DMP, advantages, limitations and risks.**

### **1.1. Expectations for the Personal Medical Record so far**

-In the eyes of a number of healthcare providers, the concept of a "Personal Medical Record" means a medical record to be shared among members of the medical professions. Doctors are inclined to think of it as a tool for professional use. They see it as being useful insofar as all relevant information is accessible to health carers who need to use it (the broadest possible access and the least possible masking). They suggest that a part of the shared medical data record could constitute the personal medical record. They feel that merging the two types of records (for professional use and for personal use) might very soon make the whole system unmanageable.

In this way the Personal Medical Record does respond to the need for improving information-sharing among members of the medical professions and any misgivings are mainly focused on the actual IT instrument itself which, as it becomes increasing complex, could be time-wasting and make data inaccessible (too long and too complicated to obtain; locking out by data protection systems, etc.)

- For users and other healthcare actors, the DMP is a medical record which belongs to the person receiving care. This is a record for the patient, hosted by a site. It contains computerised medical data concerning a patient (correspondence, test results, etc.). Any doctor *who has been authorised by the patient* may access it. Doctors can add to the record but it is under the patient's control.

Based on these two different approaches, the planners and potential users of the DMP have listed the advantages, the limitations and the risks attached to it, which can be summed up as follows:

### **1.2. Expected advantages:**

- Enable patients to make their medical records available to any healthcare provider (particularly in the case of a chronic disease with multiple carers) and at any time: even in an emergency, even when patients are unconscious or away from home;

- Avoid duplicate prescription of redundant tests (reducing discomfort for patients and cost to society);
- Help to educate patients (better informed patients take better care of themselves);
- Encourage welcome changes in medical practitioner behaviour (learn to communicate with other health carers, exchange information and review existing medical routines).

### 1.3. Notable limitations:

- **The DMP will not be a replacement for a professional medical record:**
- It seems impossible to demand that it be exhaustive (if only because of the right of patients to mask certain kinds of data).
- Certain patients might prefer to remain in ignorance of the diagnosis of a serious disease or of overly technical results of tests: how can they be protected?
- Information given to patients on an unfavourable diagnosis or prognosis should only be included in the DMP after the diagnosis announcement procedure is completed.
- No one is in fact ready to embark on this new system.
- It is not clear that the DMP will help to lower costs significantly (cost of setting it up, a healthcare system which is at present prescription-intensive, etc.).

### 1.4. Potential risks listed:

- The risk of impairing confidentiality of sensitive data and of resulting discrimination;
- The risk of creating data banks without knowing what use could be made of them in future by the pharmaceutical industry, insurance companies, security services and the State;
- The risk of overly restricted use of computerised records:
  - if data is inaccurate or incomplete or too difficult to locate, most people will consider the DMP to be useless
  - if doctors/health carers and patients themselves are not willing players in the creation of this new tool, they may well be more aware of constraints than of advantages.

## 2. Prevalence of the principle of autonomy over other ethical principles.

### 2.1. The status and position of autonomy in the decision process

Autonomy is the capacity to choose freely, without any kind of constraint or pressure. It includes informed consent but is not restricted to it. To be autonomous means deciding to follow a course and be its prime mover. There is the intention to participate in a decision instead of just complying with what is on offer.

Insofar as the DMP facilitates patient access to information relevant to their own treatment pathway it can be said that it helps to enhance their participation in the medical decision-making process. It is a factor in favour of more effective “therapeutic cooperation”.

But does this mean that ensuring autonomy is an *absolute priority*, meaning that no other principle must be allowed to impede or limit it? Or should it

be granted *only relative priority*, which supposes that this principle must be considered *first and foremost* but may sometimes be qualified by other ethical requirements? To what other ethical imperative can the principle of autonomy be justifiably opposed if an individual subordinates a part of his autonomy to the community?

## 2.2. Autonomy and solidarity

When economic resources are scarce, efficient management of the healthcare system is both a public health requirement (the quality of care depends on it at least in part) and an ethical obligation (not wasting public money amounts to not compromising the health of those in need and of future generations).

Respect for individual autonomy must therefore be measured in the light of the principle of solidarity which may moderate it. It is legitimate for a society to require the beneficiaries of the healthcare system to use it responsibly, to fight medical nomadism and redundant medical tests. **Healthcare comes at a cost and the management of this cost is not just a question of economics or policy: it is also an ethical issue.**

The computerisation of healthcare data (including the DMP) must comply with both the principles of patient autonomy and of solidarity. **It is precisely in the name of a requirement for national solidarity that society can rightly expect that the DMP will not aggravate the public health expenditure deficit.** The possibility of wasted economic resources is all the more of an ethical issue because it necessarily takes place at the expense of other health sectors which could have benefited from these resources.

Respect for the principles of individual autonomy and of collective solidarity can only be reconciled if patients see in the electronic tool a vector for improved quality of care. For patients to subscribe fully to a paperless system of communication and consent to a procedure based on electronic sharing of the contents of their medical records, it must be clear that the first priority is the improvement of their health, through better management of their medical conditions. Users will be motivated if it is clear that they will benefit from the system, for example by speedier and more efficient admission procedures (in the event of hospitalisation in an emergency).

The possible opposition between respect for individual autonomy and the political will for more rational management of healthcare costs could well become acute if the objective of improving the quality of care was subordinated to other expectations, such as managerial control by administrative bodies. In the Committee's opinion, **a project aiming primarily at reducing the national sickness insurance deficit (to which would be added the possibility of penalising patients masking some of their data) should be avoided as it would pose an irreversible threat to the credibility of the project.** However sophisticated it may be, an IT project is bound to miscarry if it does not integrate the human factor, i.e. strong and positive motivation on the part of all the players in the system, both practitioners and users. **Attempts**

**to encourage adoption of the system by all concerned through punitive action would probably be counterproductive.**

Similarly, refusing the right to mask some of the data could generate a climate of mistrust in the public mind and wreck hopes of making the scheme profitable.

## **2.3. Tension between the objective interests of patients and respect for patient autonomy**

### **2.3.1. Imperative of efficacy of the tool *versus* the right to mask data**

If exercising autonomy turns out to be contrary to the patient's best interest, should it take second place after protection of the patient in the name of the principle of benevolence? In certain cases, patients may use their right to mask data unadvisedly (if only because they do not fully understand the medical information they have been given). In the event that the expression of patient freedom turns out to be patently contrary to the patient's best interests, should the principle of patient autonomy be superseded by the principle of patient protection in the name of benevolence? Is it ethically acceptable to consider that patients would be, so to speak, "protected against themselves"?

It goes against the grain to respond in the affirmative to such a question. Our ethical and judicial culture is characterised by a tendency to give supremacy to the principle of autonomy over other principles. This is due to the notion that protecting patients from themselves (even in the name of "assistance to a person in danger") can give rise to the kind of excess which the Committee warned against in its Opinion n° 87 in 2005 on treatment refusal<sup>2</sup>.

The right to mask data complies with the principle of respect for individual autonomy. Would it be advisable and possible to qualify that right by requiring patients to exercise it only with the support of a doctor? While it is clearly recommendable that the relationship between patient and doctor be sufficiently trustful for them to be able to discuss whether such or such an item of information should be masked, anything stronger than this guidance seems hardly appropriate.

### **2.3.2. The inherent paradox of the DMP**

This point is the result of the divergent views held so far by those who designed the DMP project. The successive name changes of the personal medical record (first called the "*shared* record", then renamed "*personalised* record", before being known by its present denomination) is evidence of the fact that the scope of patient prerogatives has been appreciated in different ways by the proponents of the project.<sup>3</sup>

<sup>2</sup> CCNE Opinion n°87 on "Treatment Refusal and Personal Autonomy", April 14, 2005, [www.ccne-ethique.fr](http://www.ccne-ethique.fr),

<sup>3</sup> It is worth noting that the DMP is not a record for healthcarers nor is it the hospital's record. It only contains some partial items which are "transcribed" by the healthcarer. Nor should it be confused with the pharmaceutical record, with the file for the national health system's reimbursement procedure or the files made

Summing it up, the DMP was viewed from two different angles: on the one hand it was seen as an instrument *in the service of professional healthcare* in the interests of patients and of society; on the other it was viewed as a tool *in the service of patients* whose medical management often suffers from poor coordination between healthcare providers.

Both of these versions of the DMP are likely to be unpopular, but for different reasons:

- If the DMP is a tool in the service of professional healthcare providers, it runs the risk of being redundant with other records (electronic or otherwise). Unless our fellow citizens decide to become massively and constantly mobile (and therefore likely to consult medical practices all over the entire country on a regular basis) there does not seem to be much need for records to be unique and centralised.

- If, however, the DMP is intended to be a tool allowing patients to play a more active role in the management of their disorder, it is allowable to wonder whether the legal obligations regarding the protection of health-related data and privacy, together with the ethical imperative of the principle of autonomy, would not detract from the potential efficacy of this tool. Even supposing that the majority of patients only infrequently use masking, the simple fact for practitioners to know that masking exists at least in theory could be a disincentive. Why bother to use time that could be spent on clinical pursuits to enter into an electronic file data which may well be exposed to masking? What would be the use of a records from which the person concerned might decide (based on what criteria and what expertise?) to erase certain items of information which could be essential to his or her medical management?

Masking is not the only kind of care-quality problem arising out of full patient control over the information included. An emergency procedure (commonly called “*bris de glace*” in France – like the “break glass” procedures of alarm systems) for access to medical records via a secondary healthcare provider is a further illustration of the difficulty. The system allows healthcare providers to access a patient’s medical record in a life-threatening situation and when the patient is unable to give consent. The emergency must be authenticated retrospectively. If however the person concerned had previously made known “express opposition to records being consulted or added to in such a situation”<sup>4</sup>, clinicians are not allowed to oppose that decision and in these circumstances, accident and emergency staff will encounter a “firewall” if they seek to access that patient’s medical records.

Moreover, for the DMP to be able to facilitate decisions in an emergency (an objective that several reports highlighted), it would presumably be necessary to provide a more precise definition of the body of data which would be essential for that purpose.

**Masking and opposition to the emergency procedure are expressions of a principle of autonomy which, if respected, could be detrimental to the patient’s best interests.** An unprecedented issue also arises out of these two possibilities. In a conventional situation, the law states that people are free to refuse medical care and refers to the principle of respecting their wishes in the framework of a discussion with doctors who can — and are even duty

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up for the healthcare networking systems (often regional). While it is meant for professional purposes, it is also a “personal record” which is “available” to each socially insured patient and is related to the rights of sick persons and users of the public health system as set out in the law dated March 4, 2002.

<sup>4</sup> Article L161-36-2-2, Social Security Code



bound — to attempt to convince them that they should accept treatment<sup>5</sup>. In this particular case, the procedure could be rather more automatic, or even arbitrary, since the patient would not necessarily have been advised on masking or opposing the “*bris de glace*” procedure.

### **3) Should *coordination* be granted primacy over *quality* of care?**

Among the objectives assigned to the DMP by the August 13, 2004 law (fostering coordination, quality and continuity of care), should primacy be given to coordination, the other two concerns being very directly dependent on it? <sup>6</sup>

Users of the healthcare system and members of the medical professions agree on regarding coordination as a priority in view of the complexity of certain treatment pathways and the variety and number of healthcare providers who have a role to play in them. Furthermore, part of the economic impact expected from the DMP would be due to better coordination of care.

For that objective to be attained, it would not always be necessary for the patient’s record to contain every health-related item of data as the DMP’s original concept stipulated. It could be possible to devise a more technical medical file (containing essential clinical data, diagnoses, medical tests, identity of healthcare providers involved in treatment) without breach of the principle of patient autonomy regarding the contents of the file.

But would the issue of the motivation for additions to the DMP be solved by refocusing on the *coordination* of care? It is not rather too much to expect from a computer-based tool that it should foster a spirit of cooperation between potential users? **Coordination between partners in the provision of care supposes a mutual desire to cooperate at the outset: this is the weak point of a personal medical record that all healthcarers would be *obliged* to use.**

It is of course true that there is no obvious pragmatic solution to the problem of motivating healthcare providers to reinforce their cooperation. However, to believe that a computer-based system will inspire them with a greater desire for cooperation is perhaps illusory. **It would seem ill-advised to place too much faith in the potential of this electronic tool to raise an appetite for cooperation when, for it to work at all, a will to cooperate is itself a pre-requisite.**

For the users of the system, the question arises of the difference between people affected by the kind of illness that could really benefit from an improvement in the coordination of care (for example, certain chronic diseases) and the rest of the population who only infrequently come into contact with the medical community. The DMP concept presupposes a population that sees itself through the prism of sickness, if not currently, at least potentially.

It could be said that despite legal safeguards and rational explanations on its usefulness for the coordination of care, the DMP only concerns a restricted section of the population. There is reason to wonder whether, in present circumstances, the DMP project is postulating the

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<sup>5</sup> Except in end of life circumstances as provided in the April 2005 Léonetti law.

<sup>6</sup> The objectives are very closely related but do not entirely tally. Very frequently the *quality* of care does depend on good *coordination* but doctor may well be able to look after a patient competently without the benefit of health-related data previously accumulated by other colleagues.

existence of a society which is more fictional than it is factual (or at least is not currently realistic), in which everyone has an internet connection, wishes to access personal records, understands the medical data they contain, remembers the access codes and does not disclose them to anyone else.

On this subject, to speak of the “holder” of a DMP describing anyone and everyone, regardless of situation or time of life, can only be for the sake of convenience. To see yourself as the “holder” of an electronic record remains a purely abstract notion for someone who is not involved in a prolonged course of treatment.

Coordination of care can only be improved by patients who are concerned by the lack of that coordination and the effect it has on them (which is an issue often raised for example by people with chronic diseases). This means that **improving the coordination of healthcare, and thereby its quality, is a realistic objective on the condition that it is based on willingness.**

#### **4) Protection of confidentiality and risks in connection with computer vulnerability.**

Increasing computerisation of medical data is taking place in a cultural climate of mistrust. The notion that the benefits of easier inter-personal communication are offset by increased vulnerability is very widespread.

- Firstly, the history of computer-based communication shows that, despite precautions taken by programmers, it is still possible to gain unlawful access to confidential information. Information technology has the formidable power of making the transmission of data much easier<sup>7</sup>. There are still fears that personal health-related data could “travel” over the internet and be accessed by, for example, insurance companies or potential employers.

- Secondly, using computers is not always an entirely reliable procedure. There are worrying episodes (computer theft or breakdown, “fatal” errors when saving data, lost or corrupted files, viruses, complex procedures and perplexing computer jargon, etc.) And perhaps IT security itself is a source of anxiety for both the medical community and patients (“forgotten” codes, key changes, availability of facilities and time needed, etc.)?

- Another reason for mistrust is due to the fact that access to computer-based records could be damaging to people in their relations with insurance companies or banks.

These dangers require in-depth reflection on the part of competent authorities regarding the kind of information that should not be included in the DMP, or that should only be included if specific precautions and safeguards were used (information concerning parents and collaterals, genetic characteristics, mental disorders, behavioural data, etc.). The length of time for some data to be retained in the file could be limited (e.g. temporary behavioural disorders, particularly in childhood or during adolescence). All the actors concerned, CNIL (French Data Protection Authority) particularly, should participate in this study.

#### **5) The danger of clinical concerns giving pride of place to technicalities**

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<sup>7</sup> See on this point the National Consultative Ethics Committee’s Opinion N°98 on “Biometrics, identifying data and human rights”, dated June 20, 2007, [www.ccne-ethique.fr](http://www.ccne-ethique.fr)

- The history of technology shows that innovations are rarely confined to their original purpose. The personal medical record is only one part of a new system for medical management which includes in particular computerised prescriptions. Although the Ethics Committee approves its gradual adoption by healthcare institutions, it has already had occasion to underline the dangers of electronic aids to medical prescription<sup>8</sup>. The Committee remarked in particular on the risk of adding a third party, i.e. the computer, in the caring relationship between doctor and patient. The “technicising” of medicine can enter into conflict with the relational and human element which is so essential for “quality” clinical care.

**This is to say that the ease of communication and data processing provided by computers should not do away with the need to exercise critical judgment. On the contrary, their presence makes it all the more necessary.**

Other considerations can damage the care relationship. Electronic promptness can short-circuit the deliberate pace needed to disclose an unfavourable prognosis.

## **6) The use of information for scientific purposes**

The Ministerial referral questioned the Committee on risks inherent to the computerisation of health-related data and also on using such data for research purposes. This could refer to biomedical research or public health enquiries. Clinical and epidemiological research generally requires systematic acquisition of data pre-defined according to the object of the research, in standardised form. It rarely uses medical records, in the usual acceptance of the expression, since they only contain information selected by the primary care physician and such information may vary, for the same kind of patient, with the doctor concerned. Some examples, such as the General Practice Research Database (GPRD) in the United Kingdom, do show however that unconstrained acquisition of medical data can lead to quality scientific research, in particular in the field of pharmaco-epidemiology. As regards the DMP, it does not seem likely that it would contain the prerequisites for the potential creation of a database useful for research.

Should research be based on the DMP, it would obviously have to comply with the law on “security and liberty” regarding the processing of health-related data for the purpose of research. Identifiable data contained in the DMP must not be released, unbeknown to the patient, for research purposes.

*A priori*, the DMP could be the source of morbidity statistics for use in public health studies and it should be possible to process DMP data totally anonymously. However, this is a theoretical possibility. The epidemiological validity of morbidity statistics would depend on the general architecture of the system. For example, if patients are given freedom of choice for hosting their DMP, valid regional data will be very hard to come by. Furthermore, the overall exploitation of anonymised DMP data may turn out to be extremely complicated.

## **7) Summary**

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<sup>8</sup> See on this point the National Consultative Ethics Committee’s Opinion N°91 on “Ethical issues arising out of computerised hospital prescriptions and patient records May 2<sup>nd</sup>, 2006, [www.ccne-ethique.fr](http://www.ccne-ethique.fr)

**\*The risks connected to the Personal Medical Record that the Minister for Health's referral requested CCNE to identify and elucidate can be summarised in the three following points:**

**- The risk of economic failure in the event of DMP extension to the population at large:**

As CCNE recently had occasion to underline in its Opinion n° 101 on “Health, ethics and money”<sup>9</sup>, concerns for ethical issues and for reducing health-related expenditure cannot be considered separately. When available resources are used wastefully, a climate of frugality sets in with, as an indirect result, a poorer quality of care. For this reason, **there would be no ethical objection to giving the DMP the task of lowering the public health-related deficit.** But what needs to be underlined is that if there is no noticeable improvement in the quality of care, economic efficacy would need to be demonstrable. Should the DMP turn out to be an economic failure a serious ethical issue would be raised as it is very clear that the resources in time and money that will be needed for its implementation could have been used to improve the performance of the defective components of our health system.

**- The risk linked to masking if the DMP is made *mandatory* and not *proposed* for use on a voluntary basis:**

For reasons of collective solidarity, we are obliged to limit unnecessary expenditure caused by poor healthcare coordination (repeated tests, etc.). But any limitation — even limited — on masking rights, which would challenge the principle of personal autonomy would be unwise.

It cannot be denied that giving unconditional support to masking rights would seem at first sight to be depriving the DMP of some of its usefulness. However, the use of masking *without any reference to the primary care physician* is only virtual. **If, in fact, use of the DMP is on a strictly *voluntary* basis, masking may be only residual.** For a climate of trust to be created, time and effort must be devoted to providing the education that the future holders of a DMP could gradually become familiar with. **For the DMP to be adopted, it should not be made mandatory for everyone; it should only be on offer for those who want it.**

**- The risk of weakening the clinical and confidential dimensions of medical practice**

The DMP cannot be supposed as having a neutral effect on the doctor-patient relationship. It can of course provide diagnostic clues to the doctor and thereby facilitate their interchange; in this regard it complies with the principle of benevolence. There is however a risk of malfeasance if, insidiously, the DMP were to lead to diluting or even eliminating altogether the intimate doctor-patient dialogue and the medical history process. There would be a risk of the patient's management becoming overly determined by virtual data made available to the doctor.

Apart from the care relationship issue, the computerisation of sensitive personal data, as health-related data assuredly are, can worry some patients to the point of having a negative

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<sup>9</sup> CCNE, “Health, ethics and money: ethical issues as a result of budgetary constraints on public health expenditure in hospitals”. Opinion n°101, Nov. 7, 2007, [www.ccne-ethique.fr](http://www.ccne-ethique.fr)

impact on their quality of life. The DMP is confronted with a difficulty in this respect which is not specific to it. More generally, it relates to our society's capacity to ensure the secure transmission of every kind of electronic data. The CNIL's role in this connection will be decisive.

### **Conclusion and proposals:**

\*The Committee, on the whole, is of the opinion that the DMP, in its present form, will not meet the goals set for it, i.e. improving the effectiveness and quality of care through better coordination and thus making better use of expenditures by keeping costs down to their present level or further reducing them.

The main reasons are as follows:

1/ Priority has been given to the computer-related characteristics of the record which is supposed to achieve the stated objective by collating purely clinical and biological data, but the clinical dimension of the doctor/patient relationship — which is essential particularly for a possible revision of the diagnosis, or its periodic review — is missing;

**2/ The ethical requirement for compliance with a patient's right to mask some of the data in the record is incompatible with the defined objectives.**

**3/ In the present state of the technology, there is no absolutely fail-safe electronic data processing system;**

4/ There is a considerable risk of loss of confidentiality of the DMP contents because of the ever-present possibility of data cross-checking through other electronic records;

5/ There is a risk of compromising individual liberties in favour of certain institutions, in particular administrative and financial bodies or insurance companies, in the event of non-communication of the contents of a record which is generally available;

6/ The excessive cost of setting up the system on a nation-wide scale compared to, inter alia, expected results and the existence of other public health priorities which are cannot be funded as yet.

\*The Committee however is in favour of setting up a DMP which could facilitate the treatment of patients suffering from protracted disease or disability. A DMP containing essentially the data needed to care for such patients could be helpful to healthcare providers and to those using the health system. Users could furthermore benefit from the assistance of patient support groups, and in the case of children or multiple disabilities, so could their families.

\* The DMP, which is designed for users with intellectual and practical competence, is not appropriate in its present form for socially excluded and/or disabled people. There would be a need to rethink the DMP so that it could facilitate treatment for existing conditions and preventive care to such patients, without undermining their autonomy.

\*If DMP use was entirely voluntary the issue of masking rights would be negligible.

In consequence, the Committee makes the following proposals:

1. **In its present form, the DMP is not suitable for universal adoption on a national scale since it is not compatible with its stated objectives although the cost of implementation will be very considerable;**
2. **The DMP could be proposed in the following circumstances:**
  - a) **To volunteers;**
  - b) **To patients with chronic diseases whose condition requires attention from a number of healthcare providers over a long period of time;**
  - c) **To those who are aware that they would benefit from the creation of a computer-based record which could help provide them with optimal diagnostic and therapeutic management by healthcare professionals, in particular because of the exhaustive nature of the information it contains;**
  - d) **To those who are in possession of the entry key to their record and are capable of authorising access to it only to those they select and, apart from their intimate circle of family members and trusted friends, only to persons who are bound by rules of confidentiality;**
  - e) **To those who do not run the risk of penalty should access to the medical record, which they alone and persons they have authorised know to exist, be denied to any authority or institution;**
  - f) **Once initial implementation has been put into effect in pilot areas, in particular those where there has already been some degree of experimentation in this domain;**
  - g) **After evaluation of results in regard to the stated objectives at the end of a three to five year period, according to a set of criteria to be defined in the implementation phase of this new DMP;**
  - h) **Before possible extension on a national scale, but still exclusively to volunteers.**

Paris, May 29, 2008

## Bibliography

- Reports

Inspection générale des finances / Inspection générale des affaires sociales / Conseil général des technologies de l'information. Rapport sur le dossier personnalisé (DMP) (*Report on the DMP*) by Y. Boaretto, M. Gagneux, F. Cholley et al. Paris, Inspection générale des finances, 2007

<http://www.ladocumentationfrancaise.fr/rapports-publics/074000713/index.shtml>

Commission nationale de l'informatique et des libertés (CNIL). Conclusions des missions de contrôles relatives à l'expérimentation du DMP. (*Conclusions on DMP experimentation*) Paris, CNIL, 2007

<http://www.cnil.fr/fileadmin/documents/approfondir/dossier/sante/CCL-contrôleDMP-VD.pdf>

Fagniez P.L. Le masquage d'informations par le patient dans son DMP. (*Data masking in the DMP by patients*) Paris, Ministère de la santé et des solidarités, 2007

<http://www.ladocumentationfrancaise.fr/rapports-publics/074000115/index.shtml>

Door J. Rapport d'information déposé par la commission des affaires culturelles, familiales et sociales de l'Assemblée nationale sur le dossier médical personnel. (*Parliamentary Committee for Cultural, Family and Social affairs Report on the DMP.*). Paris, Assemblée nationale, 2008

<http://www.assemblee-nationale.fr/13/rap-info/i0659.asp>

Malzac P., Le Coz P. Rapport de la « Commission casuistique » de l'Espace Éthique Méditerranéen de Marseille (*Report by the Marseilles Mediterranean Ethics Agency*) (EA 3783), avril 2008

<http://www.medethique.com>

Gagneux M. Pour un dossier patient virtuel et partagé et une stratégie nationale des systèmes d'information de santé : recommandations à la ministre de la santé, de la jeunesse et des sports. Paris, Mission de relance du projet de dossier médical personnel, (*Virtual and shared patient record: recommendations to the Ministry of Health*). May 2008 [http://www.sante-jeunesse-sports.gouv.fr/IMG/pdf/Rapport\\_DMP\\_mission\\_Gagneux.pdf](http://www.sante-jeunesse-sports.gouv.fr/IMG/pdf/Rapport_DMP_mission_Gagneux.pdf)

Conseil national de l'Ordre des médecins. L'informatisation de la santé : le livre blanc du Conseil national de l'Ordre national des médecins. Paris, Ordre national des médecins, May 2008 (*White paper by the French National Medical Association on Health and Computerisation*)

<http://www.web.ordre.medecin.fr/presse/cnomlivreblancinformatisation.pdf>

- Publications and articles

Dupuy O. La gestion des informations relatives au patient : dossier médical et dossier médical personnel. Bordeaux, Les Etudes hospitalières, 2005 (*Management of patient-related data: medical record and the DMP*).

Picard S., Pellet J., Brulet J.F., Trombert B. Les aspects juridiques et éthiques de la protection des données issues du dossier médical informatisé et utilisées en épidémiologie : un point de la situation. *Santé publique*, 2006, pp. 107-117 (*Legal and ethical aspects of the protection of data in computerised medical records used for epidemiological purposes: present status*).

Dossier médical personnel : aspects juridiques et déontologiques, Actes du Congrès, Nancy, 2005. *Revue générale de droit médical*, 2006, n° 20, pp.53-246 (*The DMP: legal and deontological issues*).

Duguet A.M., dir. Dossier médical et données médicales de santé : protection de la confidentialité, conditions d'accès, échanges pour les soins et la recherche, 10<sup>ème</sup> séminaire d'actualité de droit médical, Toulouse, 2005. Bordeaux, Les Etudes hospitalières, 2007 (*Medical records and health-related data: protection of confidentiality, conditions for access, exchange of data for care and research*).

Brodin M. Informatisation et confidentialité des données médicales. Laennec, 2007, n° 1, pp. 12-22 (*Computerisation and confidentiality of medical data*).

Le dossier médical personnel, dossier coordonné par C. Collin. *Actualité et dossier en santé publique*, 2007, n° 58, pp. 17-56 (*File on the DMP*).

Dreifuss-Netter F. Dossier médical et DMP. *Hôpitaux magazine*, 2007, n° 3, pp. 31-35 (*Medical Records and the DMP*).