National Consultative Ethics Committee for Health and Life Sciences

Opinion n°91

Opinion on ethical issues arising out of computerised hospital prescriptions and patient records

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Outline

Introduction

Since 2004, several members of the medical professions working in the Paris public hospital system (Assistance Publique des Hôpitaux de Paris) referred to CCNE regarding the ethical aspects of using medical prescription writing software. This data processing tool is now being used by various hospital departments, and for some hospitals it is even used to prescribe medical tests and drugs which are managed (or in some cases prepared) by clinical and pharmaceutical personnel.

The ethical issues underlying the experimental use of computerised drug prescriptions can be summed up in the following questions: Is patient safety compromised due to errors arising out faulty use of the software programme? In the present state of the art, is it too early to express an opinion on whether the use of software should be extended to the entire hospital environment? Are there legitimate reasons for delaying such technological reform? When it is used on an experimental basis, should the use of computerised prescription writing be brought to the attention of patients?
It is obviously not within the Committee's competence to make a pronouncement on the reliability of any particular item of software or hardware, particularly since such devices may well, as time goes by, be modified or improved or on the contrary found to be defective at a later stage. Our purpose is to present, in an Opinion which aims to be of a general nature, a list of all the advantages and drawbacks that the process of computerisation may bring about in the management of patients within a hospital environment, before going on to make a certain number of recommendations aiming to improve the chances of success for institutions considering the introduction of this kind of technical support.

1) Description of the system

Computer assisted prescription writing goes hand in hand with the computerisation of patient records. Computerised prescriptions do not simply consist in converting writing into electronic input. Software for computer assisted prescription writing are programmes which carry out various functions with the purpose of optimising the quality of a prescription. Before that is done, an electronic file must be created which must be sufficiently flexible to be able to adapt to the characteristic needs of each hospital department. With such a tool, prescribing practitioners can be acquainted at any time with the full contents of medical records stored in the database. In certain departments (anaesthesia, resuscitation, etc.), software must be able to interface with all the equipment in the healthcare unit and with other computerised systems within the hospital so as to enable data import and export.

Equipment basically includes a patient computer, desktop computers (for doctors' offices and nursing stations) and servers to archive patient data (one server for patients under treatment in the unit concerned at the current time and another for all patients previously hospitalised in the unit).

Data acquisition operations include: updating medical and nursing observations, prescribing further tests, medical prescription writing of pharmacological and instrumental treatment (drugs, infusions, biomedical equipment, etc.). The full medical record may be displayed at the patient's bedside. Display options available are varied and suited to the needs of each user (graphs, tables, histograms).
Computers connected to the department's network can also proceed with data acquisition and display. These computers are installed in doctors' offices and nursing stations so as to perform certain calculations (severity scores, nursing load scores, records of procedures for the purpose of tariffing, work-ups when patients enter or leave the department, etc.)
Digital media which is completely separate from the network is used for the daily back-up of all data. This system can also be used to print hard copies of files in case of system breakdown.
Information stored in the database is used for patients under treatment in the hospital and for patients who are no longer present in the unit, in full compliance with the recommendations of the Commission Nationale de l'Informatique et des Libertés (CNIL). (French Data Protection and Privacy Authority).

The database exploitation programme for hospitalised patients is the source for production of a full medical record meeting four requirements:

- Automatic registration of incidents, in particular nosocomial infections,
- Automatic detection of complications affecting patients,
- Semi-automatic recording of hospital admission data,
- Complex calculations for nursing load scores, automatic pharmaceutical order forms, etc.

Data recorded for all patients can be consulted for the purpose of keeping monthly or annual performance indicators which are essential for the quality control of a department. The full set of recorded parameters can be examined so that patient management, with particular emphasis on healthcare quality, can be monitored closely and precisely. The tool is also valuable for quality management of clinical studies being undertaken in a department.

Computerisation of patient records together with computer assisted prescription software goes way beyond simply digitising a handwritten file; it entails complete reorganisation of a department which raises two issues: that of the information supplied to patients who are to be treated in a computerised healthcare unit; and the motivation of healthcarers, it being clear that the advantages derived from computerisation must be obvious to everyone concerned in view of the cost of such an operation. Time saving and reducing the number of errors in medical prescriptions (in particular as regards the detection of medication incompatibilities) must be the kind of progress that everyone wants if user motivation is to be on a par with the economic investment involved.

2) Information provided to patients

At first sight, it appears obvious that the issue of information given to patients hospitalised in a unit in the process of "experimenting" is not related to the safety and

reliability of software for drug prescription and dispensing. On the one hand, we are faced with an ethical dilemma (can people who are directly concerned by an innovation be left in ignorance of it?), but on the other hand we have a purely technical problem (is the software reliable?). Nevertheless, these two question (information given to the patient and software reliability) are closely connected for two reasons:
- If the software is unreliable the question of whether patients should be told no longer arises since it is obviously unethical to knowingly endanger people's health. The medical profession is still governed by the Hippocratic credo "*primum non nocere*". If from the outset the computer tool violates the principle of not doing harm, the issue of information is irrelevant.
- Patient acceptance of a new form of management (computerised or otherwise) very much depends on what information is given to them. If for example, information given to patients only mentions minor *known* risks, it will obviously not have the same emotional impact as it would if it included *potential* risks as well. For instance, the risk of a power breakdown can be mentioned (as well as the steps taken to ensure patient safety in such an event) if the department has already had occasion to suffer from such a breakdown. However, the risk of a general electricity outage which would lead to the loss of data backed-up in a neighbouring healthcare establishment is a purely potential risk which hardly needs specifying to patients, and all the more so since power generators can avoid such a disaster scenario. Generally speaking, at the present time, power generation redundancy is fully integrated in the plans submitted by computer service companies.
On this risk issue, the Committee has already had occasion in Opinion n° 79[1], to underline the harmful effects that would be inevitable if information supplied to patients were to include the *potential* risks of an experiment. The Opinion stated that only "serious and irreversible risks must be clearly stated to the participant," whereas "possible risks do not demand any further precaution than being correctly evaluated. The important aspect is the requirement for transparency, not futile emphasis on uncertainty"[2].
However, experiments with software raise a particular ethical issue. The patient in this case cannot request a prescription on paper so that this is simply information and not a request for consent. The need for such information seems to be even less obvious since the subject is safety rather than information.
The problem that still needs attention is the exact evaluation of the benefit/risk ratio, with the slight difference that one must be certain that using the software does not require skills which are so advanced that the probability of human error would be increased.

3. Hospitals and computerisation: the issue of staff motivation

The intrinsic reliability of a computerised prescription system cannot completely eliminate the possibility of human error when using it. The history of technology shows that a data processing tool can be both practical and easy to use without necessarily raising much interest on the part of those for whom it was designed. The fact that it is

[1] Opinion n° 79 : "Transposition into French law of the European Directive relating to clinical trials on medicinal products: a new ethical framework for human research." Sept. 2003.
[2] *Ibid*.

potentially usable does not mean that it will in fact be used[3]. Nothing is in itself particularly difficult or easy. A software programme which an experienced computer user finds easy to handle may appear too complicated to the uninitiated. For a computer assisted prescription programme to be effectively used, all healthcarers must be motivated since it would be inconceivable to have some carers continuing to use handwritten prescriptions while others had already accepted the change to a computerised system.

Motivation on the part of carers depends on how they perceive the benefits they expect to obtain compared to the possible risks (for both carers and patients) and the advantages as regards health and safety they believe they will get from the system compared to the usual prescription procedures. Quite obviously, one cannot encourage the use of technical innovation, however sophisticated, for the sole reason that we have now entered a new cultural era dominated by society's total conversion to information technology and that no institution can possibly dispense with it. That technological advances are not necessarily synonymous with ethical improvement is a truism. And although advances in profitability and performance are sufficient in themselves to justify the computerisation of communication systems in corporations and administrative departments, they cannot be adopted without due precaution in the hospital environment[4]. All the more so since experience has shown that the increasing technicality of medicine sometimes enters into conflict with the human and relational components which are inherent to medical practice[5]. However, computer assisted prescription requires "a generalisation of the use of information technology by the

[3] The introduction of new technical tools in a sector of human activity may well come into conflict with the logic and perceptions of those for whom it was intended. One illustration is the disastrous response that met the French national railway company (SNCF) when they tried to launch SOCRATE (Système Offrant à la Clientèle des Réservations d'Affaires et de Tourisme en Europe - a booking system in Europe for business and leisure travellers) in the 90s. This booking system was never integrated into the existing ticket selling system. Regarding its failure, see the report of the Cour des Comptes (Court of Financial Auditors), www.ccomptes.fr 1996: *"There was some confusion in the organisation of this project as regards the respective roles of the final user, the contracting authority and the project manager. The methodology used for the development of the SOCRATE system was faulty in that attention to quality was too tardy and qualification testing was poorly designed and truncated. The problems arising out of feeding "passenger data" into the system were seriously underestimated; for example, the number of trips per connection introduced into the SOCRATE system was limited to 4,000 although ten times as many at least were needed. Finally, tests before entry into service were insufficient. The total cost of the system amounted in fact to 2.1 billion Francs in 1988, i.e. more than double the estimate made at the time the project was launched (...). The decision to run the system full scale was premature: although the system was a year and a half overdue, SOCRATE was obviously not ready for the purpose when it was put into service. External communications were totally deficient and internal training was faulty. Dialogue between the SNCF and user associations was too formal and communications with the public at large were defective. As regards the training provided for the sales force, it left much to be desired, particularly as regards learning to operate the SOCRATE system.").*

[4] As regards the question of performance in a medical environment, cf CCNE's Opinion n° 31 (Performance and Health, Nov. 2003): "The undeniable progress that has marked the advancement of the biomedical sciences in the last few decades, the important improvements to health that they have brought about, could be damaging if the quest for exploits or performance at any cost becomes the primary consideration."

[5] The Committee mentioned this point in its Opinion n° 84, dated April 29, 2004 on the subject of education in medical ethics: "the increasingly technical nature of medicine is insidiously converting the art of healing into a process of expertise, so that there is a risk of forgetting that technology is no substitute for hospitality". (ch. I.1.b "Eclipse of the clinical side of medicine").

various medical professionals throughout the various phases of the process, including ideally at the patient's bedside"[6].

It is important therefore to understand the reasons why healthcarers may feel reluctant to accept this new method of prescribing. There are four possible causes for legitimate suspicion:

- For sociological reasons, ostensible innovation always provokes some degree of spontaneous resistance because habits have to be changed and there is a need to undergo a learning process which certain members of the group may resent if there seems to be no immediate advantage for them and their work is made more difficult. This reticence may be reinforced by the suspicion aroused by computers generally and the anxiety they generate about possible electrical outages, computer breakdowns, "fatal" errors when saving data, lost or damaged files, viruses, complex user procedures and incomprehensible computer jargon, etc. This mistrust of information technology (apart from the really elementary functions such as word processing) is not specific to the French. English language reports have underlined on several occasions that hospital practitioners were unenthusiastic about information technology, even in its most trivial forms such as the computerisation of medical records which is the essential prerequisite for computer assisted prescription writing. Tim Benson published a few years ago[7] a retrospective survey covering thirty years which revealed the low degree of motivation on the part of hospital doctors as regards computers despite major efforts made by the authorities to develop computerised management of medical records. Unlike doctors outside the hospital environment (whose interest was almost instantly aroused when such new management techniques emerged[8]), in British hospitals there is a feeling that computerisation of prescriptions does not provide any substantial improvement in the quality of care and that its contribution is exclusively administrative (rationalisation of the management of financial resources).

- The risk of misconduct. The history of information technology shows that despite all precautions taken by programmers, it is always possible to misappropriate confidential data[9]. That some member of the medical team might deliberately use his or her data processing skills with malicious intent to alter the electronic patient record on which the whole system of computer assisted prescription writing is based is at least a plausible scenario.
Generally speaking, the feeling that the more data is computerised, the easier it becomes for it to be compromised by third parties (or supervisory organisations) is not entirely devoid of truth. It must be observed on this point that computerisation is fairly

[6] Gloria Zarama-Vasquez and Dominique Vinck, *Intégration de l'outil informatique dans les services de soin. Le cas de la prescription médicale informatisée,* IPI Symposium, Autrans, 22-23 Jan. 2004.
[7] Benson T., Why general practitioners use computers and hospital doctors do not (part1: incentives), in *BMJ*, vol. 325, 9 Nov 2002.
[8] Tim Benson reports that in the last ten years only very few (4%) general practitioners remain who are opposed to the use of computers ("today almost all general practitioners have computers in their consulting rooms and are connected to the NHSnet").
[9] This is particularly true of electronic mail which is vulnerable to "hacking" and the stealth of confidential information (intrusion of the "Trojan horse" variety) cannot be altogether excluded within healthcare institutions where patient-related information transits via this mode of communication.

easy to adjust to the economics of medical practice. The criterion of healthcare quality may gradually be viewed as less worthy of consideration in the presence of analytic accounting concerns which are particularly meaningful in a society such as our own that is haunted by the problem of increasing public health expenditure.

- On a symbolic level, the intrusion of a new technological tool may be unwelcome in units that are already rife with technical devices of all kinds (alarms sounding periodically, blinking screens, background machine noise, etc.) where patients are already no more sometimes than an item in the workings of insensate machinery performing automatic monitoring tasks. Technology is unable to humanise the caring relationship and what is ailing with hospitals in this day and age is perhaps not so much a lack of equipment as a lack of sufficient staff to devote some time and attention to patients. Built to provide hospitality, hospitals are by their very nature designed to soothe human suffering which has more need of empathy and clinical skill than of electronic devices.

- Even though computer assisted prescription writing may be designed only to help practitioners, it is imaginable that it might surreptitiously end up being a substitute for the effort of coming to a decision through a process of thought. This is not a rare occurrence: because it forms a "triangular" relationship, the presence of a computer in a space designed for dialogue tends to hinder a direct form of discussion. The eyes of a user sitting behind a screen are drawn to the artificial light that comes from it. As a result, the physician's attention may be captured by the screen so that he spends more time looking at it than at the patient. This pernicious trend in the use of the computer tool reveals a possible deterioration of the relational quality of the dialogue. Instead of being a simple tool to assist decision making, the software programme for computerised prescription writing could end up being harmful to the interactive participation on the part of the patient in the therapeutic strategy which the law dated March 4, 2002 insisted upon[10].

A plan to implement computer assisted medical prescription writing therefore requires convincing arguments to gain the approval of both professionals and users of the healthcare system since there is reason to fear dehumanisation of patient management and excessive artificiality introduced into the healthcaring world. The fact that computers are still relative newcomers in the world of healthcare institutions in France is probably evidence of some muted psychological resistance which must be taken into account when a system of this kind is planned.
In the evaluation of the benefits to risk balance, it would appear that the largest obstacle to computerisation of prescriptions is seen to be the gradual slippage into excessive "mechanisation" of the medical art.

4) Benefits expected from computer assisted prescription

[10] Cf. Law N° 2002-303 dated March 4, 2002 on patients' rights and quality of the healthcare system, Art. L. 1111-4.: "Decisions regarding a person's own health are taken by that person together with members of the medical professions taking into account the information and recommendations made by them". *(Journal Officiel N° 54 dated March 5, 2002).*

The argument put forward by those in favour of rolling out a technological reform of this kind is essentially **better safety than what is provided by the conventional prescription systems.** Errors in prescribing or dispensing medicines are a permanent concern for both carers and patients. This computer tool does offer a possibility of rational programming of nursing activities via the "plan for drug administration" (PAM/Plan d'Administration des Médicaments). Carers are better able to monitor the distribution of medicines because the system is more **legible**. As a result, therapeutic prescriptions stand a better chance of meeting the demands of codes of good practices because the **traceability** of health care administration and the **validation** of care are ensured. Patient identifying data and patient consent are recorded, as are programmed hospital release dates, complete with digital identifiers and passwords.
To these obvious advantages may be added those inherent to computerised systems generally, i.e. clearly legible records and avoidance of the risk of copying errors when information is hastily noted down for written transmission. The approximation of oral communication is profitably reduced for nursing staff who are able to consult treatment protocols and improve the availability of pharmaceutical stocks.

Assuming that doctors cannot always keep in mind the characteristics of every substance they prescribe to their patients, it can be said that computerised guidance helps to improve their decisional capabilities at three levels:

- The software prescribing tool facilitates access to information about medicines; it normally alerts to interactions, incompatibilities and contraindications. The doctor would make **a selection of drugs in a database of his own creation on the basis of his particular clinical experience or that of the institution's therapeutic references**. One would not expect the software to act like a cognitive crutch. The concept of "expert system" is misleading in this respect. Diagnosing (which is part of what is called "the art of medicine") cannot be the task of a machine. The model of "artificial intelligence" is not pertinent in the context of computer assisted prescription. The software however must be sufficiently sophisticated to offer modules for assisted prescription with an indication of equivalent medicines in the case of interaction or contraindication for a given substance.

- As regards the chronology of hospital patient management, all carers in the unit can find out which doctors their patient has already consulted and what decisions were taken. In case of doubt, internal communication between medical personnel within the hospital is bound to be facilitated. By giving clear indications on screen of medication times, doses, reasons for dosage as indicated, summary of treatment, the computer greatly enhances cooperation between doctors and nursing staff who are spared the trouble of deciphering sometimes illegible handwriting.

- The doctor is usefully helped in the always delicate task of coordinating a patient's medical record (allergies, etc.) and the information concerning a particular product. For every patient, prescription is based on an electronic file which is accessible at all times whenever users need it. That is why, although the programme's functions are supported by uniformity and standardisation processes, paradoxically the computerisation of

patient management is more respectful of the pathological singularity of patients. Prescription is not **dictated** by pre-programmed data (a consensus conference that *imposes* a decision for example; it is simply **helped** by a summary table that provides instant information on evolution (in figures or graphically) of a patient's health by automatic and regular recording of clinical data displayed on screen at the bedside. Computerised prescription also complies completely with article 8 of the Code of Ethics which stipulates that "within legal limits, physicians are free to prescribe according to what they consider to be most appropriate in the circumstances" [11].

Altogether, what would seem at first sight to represent a risk of dehumanisation of human relations because of excessive artificiality could turn out to be a factor in favour of the elimination of internal dissension. Medical teams who have already tested this prescription computerisation system, as is the case of the Resuscitative Department of the Louise Michel Hospital, Evry, would not hear of returning to the old system of written records, although they readily admit that they were very apprehensive when the system was first put into service. The pilot project ongoing in this institution since 2002 also shows that the technological invasion described by some authors[12] is in fact limited to a maximum of one computer in each sickroom[13] (cf. annex).
Viewed from that angle, computerised prescription does not raise any major problem as regards information to and consent from users. Once patients were informed of the improvement in the management procedures concerning them, they would certainly subscribe to what is clearly designed solely to increase their safety while they are being cared for. If they are informed that instead of written documents information concerning their health will be noted in a high quality record - as regards legibility, reliability of note taking (observation, monitoring, prescriptions, administrative procedures) and calculation (scores, work-ups) - their agreement with the doctor who informs them is implicit. Introducing a computer into a room which is usually already full of sophisticated equipment can only appear to be one extra item in a technological puzzle with which healthcare users have now had ample time to become familiar[14].

[11] Code of medical ethics., *http--www.conseil-national.medecin.fr*
[12] Gloria Zarama-Vasquez and Dominique Vinck seem to indulge in curious prophecies on this point. (cf. *Intégration de l'outil informatique dans les services de soin. Le cas de la prescription médicale informatisée*, *op.cit.:* "This will involve tooling up with desktop computers, laptops transported on gurneys, notebook computers and an antenna network in healthcare unit corridors to connect laptops to the hospital's computer network".
[13] Equipment in service in the Department of Resuscitative Medicine of the Centre Hospitalier Sud Francilien, Evry (Resuscitation Unit directed by R. Boiteau) consists in one desktop PC at the bedside, a production server and another server for archiving, a maintenance PC, an interface network with SIH (the hospital information system) so as to exchange administrative, laboratory and imaging data, etc. with the SIH.
[14] There are other risks which cannot be ignored but should not be blown up out of all proportion. This is the case in particular of the risk of malicious misconduct. To the extent that the computer tool automatically reveals the identity of the user who must enter a personal code, it cannot be claimed that this has no deterrent capacity. Furthermore, the written form of a medical record offers no guarantee that would be lost through computerisation (the manual possibility of destroying all or part of a patient's record).
A rational evaluation of the risk that patient data becomes an open book is also required. A number of software programmes include the possibility for a medical record to be filtered according to the degree of confidentiality of the information contained in it. It will therefore be up to the Head of Department to decide what sensitive biographical data should remain inaccessible to other members of the medical team.

Experiments ongoing in France, either in an entire hospital or in one of its departments show that computerised prescription can be a step forward as regards greater healthcare safety for patients. Taking into account the risk of medical errors and approximate verbal communication between healthcare actors, the traceability of information and the alarms raised regarding medication incompatibilities provided by computerised prescription should allow for considerable progress. It would be disingenuous and intellectually lazy to put forward the argument that no one could ever evaluate scientifically the difference in quantity and severity of errors committed under both systems and to use it to discourage innovative initiatives already being taken in some hospitals.

It is important however to compare the advantages expected from a data protection system with conditions on the ground which sometimes feature some degree of dysfunction. Based on the shortcomings reported by medical teams working in an experimental site, the Committee wishes to make a certain number of recommendations as regards the conditions of acceptability of a computerised prescription system.

5) Recommendations

1) The success or otherwise of an experiment depends on the human resources and the safety of the project being proportional to the number of qualified personnel who will be working in the experimenting departments. That is why it is essential that users are given sufficient training. Training in information technology must avoid the "one size fits all" principle and respect individual capacities. It must therefore be carefully modulated with respect to the varying degrees of competence of each member of the staff. At the end of the process, all participants must feel equally comfortable with the system[15]. It is essential to avoid the trap of specialising certain members of the healthcare team who would as a result spend less and less time in clinical practice because of being confined to electronic tasks.

2) Referent healthcarers whose task would be to communicate the know-how they have themselves acquired must be assisted by the programmer and managers who are involved in the setting up of the selected software. The presence of information technology professionals working alongside healthcarers who will be training other members of their department in the hospital should help to accustom workers to the use of highly sophisticated equipment (designers and installers sometimes think that the success of an instrument is owed to its intrinsic operation capacity whereas the reasons for success are connected to the users' capacity to ingeniously adjust it to meet their own demands[16]).

3) Remembering information technology systems that failed and left a lasting impression with people who had believed in their usefulness in previous decades, it would seem

[15] The need for training will diminish with the spread of information technology competence which everyone agrees is happening very rapidly.

[16] Gloria Zarama-Vasquez and Dominique Vinck, *op.cit.*: "if performance is obtained by means of increased effort on the part of users, this can have negative repercussions on their work, their well-being, or even their health as some recent ergonomic research has shown".

essential to **programme a collegial debate between professionals concerned** so that their reasons for reluctance are clearly explained. Discussion should be encouraged between present users and staff in departments which still use a conventional (written) mode of prescription. Because one of the stumbling blocks is the feeling that the computer is counter-productive (that it wastes the time it is supposed to save), the question of return on time invested after a training phase must be one of the main points of the debate[17].

4) The most reliable way of getting healthcare professionals to trust new technology would be to organise a progressive roll-out starting with the units where prescription is easiest to manage. This progressive integration of the computer-based tool can be operated on the basis of simulated prescription experiments designed to help users get their bearings on what to do in the case of technical malfunction and to understand the complexity of a drug's circuit. It could also be done on the basis of prescriptions which — although they are computerised — also come in written form, until the professionals concerned have had a chance to become fully familiar with the technological detail.

5) After setting up such a system, **follow-up** should include a period of time for **feedback** so that all users can have the opportunity of regularly reporting on difficulties they may have encountered. At these consultative meetings, the software's rigidities and the constraints connected to its strictly rational logic should be meticulously listed and participants can describe errors and deficiencies they have come across. The elimination of hard copy should not be seen as being the final objective but simply as a measure of the efficient use of the system. The feedback procedures should help users improve the system by inventing their own headers when they were not provided in the initial version. The experimental phase of the use of software can only be considered to be complete once the medical team no longer encounters situations for which the prescription application is excessively constraining.

6) A prescription can only be dictated on the basis of the components which were accepted or even incorporated into the database by its users. It is **validated** by the fact that compared to the previous forms of prescribing (in writing), doctors and their staff have at least **as many prescriptive options** as they had before.

7) The problems encountered by a unit when using the data processing tool must be brought to the attention **at the earliest possible opportunity of all the healthcare units and hospital sites** taking part in a similar computerisation experiment. This condition supposes of course that the errors are reproducible from one hospital to another. It is therefore absolutely essential to **reduce the diversity of computer-based systems** and to arrive at a consensus on the limited number of software programmes to be adopted. This effort to achieve uniformity should take into account the existing computerised systems so as to **standardise** across the board all the operations already in operation in all healthcare establishments, at every level[18]. The Committee's task

[17] One of the points to be included in the debate should be the time saved by not having to transport physical information media from one part of the hospital to the other.

[18] In experiments carried out in various other countries, the problem of feedback of information from general practitioners to hospitals being blocked by incompatibility of systems is often mentioned, cf. recommendations made

does not include awarding prizes to the best software salesman, but it does consider as proven that quality is proportional to the degree of freedom and satisfaction that it leaves to users with, as an option for the future, the possibility of arriving at an entirely configured turnkey system.

8) If software is not sufficiently sophisticated to detect even the grossest prescriptive errors, it cannot be allowed to run in hospital departments. **Software must be able to detect prescriptive aberrations, in particular with regard to patient characteristics, not just medication incompatibility.**

9) **A spirit of cooperation is the lynchpin of a successful innovative scheme,** so that all users must be allowed to express the wish to have the system put in abeyance or remodelled if they feel they cannot cope with the problems raised by the way it operates or if they consider that it is not living up to legitimate expectations (for example if the search engine seems inadequate as regards the mass of data to be dealt with). Generally speaking, all carers must feel they are stakeholders in the elaboration of protocols as well as in the coordination of working groups. They should not, under any circumstances be viewed as simple implementers of a medical treatment prescribed by the computer. They must be able to examine in particular the plans for medication administration and make any needed modifications if, for example, they find an obvious mistake (a drug that appears twice on a printout which must not be interpreted as a double prescription) and even add to the prescription empirical annotations (drugs that have been prescribed although they may not appear on the screen, etc.).

10) Even with the most favourable outcome, i.e. perfect software performance, a close watch is essential at every level of the organisation of an experimenting unit. It would be helpful if supervision could be provided by a referent-physician assisted in every case by at least two carers who are perfectly familiar with the use of computer-based tools and their limitations[19]. Competence in this respect cannot be limited to a single person for obvious reasons: temporary unexpected unavailability, or absence for training purposes[20].

11) To achieve optimal system safety, hospitals must be authorised to acquire the equipment needed for the setting up of this technological infrastructure. **Financial constraints amount to a short-sighted policy because it is clear that over time, long-term costs are reduced in proportion to time saved.** The cost of software must not therefore be the only parameter to take into account in the choices made following calls for bids. The cost must integrate also the availability on site of the computer service companies (without any bargaining counterpart). The equity principle which

by Tim Benson in " Why general practitioners use computers and hospital doctors do not (part 2: scalabilty)", in *BMJ*, vol. 325, 9 nov 2002 : " In hospitals many different computer systems need to be linked together, requiring common interoperability standards".

[19] As an illustration, the Evry Hospital benefits from the services of a state-registered referent nurse for Material Vigilance and one for Training and Data Processing.

[20] Doctors are not *a priori* better qualified computer users than other healthcarers and quite frequently nursing staff complain that the "doctor is in charge of an instrument that he is not qualified to use". (Gloria Zarama-Vasquez et Dominique Vinck *Intégration de l'outil informatique dans les services de soin. Le cas de la prescription médicale informatisée, op.cit.)*

calls for a fair distribution of public health goods and services to all healthcare beneficiaries, cannot allow for a waste of the resources allocated to the health sector since quality information technology equipment is a source of long term savings[21]. It must be kept in mind that where countries have long ago carried out experiments involving the computerisation of medical data and made comparative studies, it was found that technological expenditure on healthcare was counter-balanced by savings in time which, taking into account the cost of hospitalisation, always adds up to financial savings[22].

12) A system of **computer services standby** on a 24/7 basis is essential in case of dysfunction. Technicians from the companies involved in the setting up of the system must be immediately available if the electronics break down or there is a blockage. Maintenance of the system must be carried out on a very regular basis to integrate new products, correct configuration errors, improve software use and data processing. A nearby healthcare establishment must be equipped to back up the computerised system.

13) Although a prescription generally contains less information on a patient's health than medical records, the greatest attention must be paid to the **confidentiality of both prescriptions and records**. However, asking each prescriber to give a password is associated with the paradoxical risk that screens will be left visible to save time. This would make it easier for an outside observer to access information which must absolutely remain confidential[23]. An adequate balance between confidentiality and ease of handling can surely be found.

In conclusion, the Committee wishes to emphasise the following points:

- An analysis of the ethical aspects involved in the decision to use a computerised medical prescription tool shows that its effect on the benefits to risk ratio is excellent. Computerised prescription writing is no longer in the experimental phase for a number of units, some of which are in France, which have definitively ceased to use handwritten prescriptions. Clarification of the contents of the prescription — which is needed if the computerised prescription system is to be made to work — is in agreement with the Code of Ethics which states that "the physician must formulate prescriptions with all due clarity, make sure that patients and their families understand them and to the best of his ability, see that they are properly implemented"[24]. It is no longer necessary to compare several software applications to evaluate risks and benefits since several simple and effective programmes already exist and have proved their worth in various units both in

[21] Medical errors are costly. Cf on this point: Institute of Medicine of the national academies, Washington, 2000; *Medication-related errors for hospitalized patients cost roughly $2 billion annually* ; Bates, D.W., N. Spell, D.J. Cullen, E. Burdick, N. Laird, L.A. Petersen, S.D. Small, B.J. Sweitzer, and L.L. Leape, 1997 "*The costs of adverse drug events in hospitalized patients. Adverse Drug Events Prevention Study Group". JAMA* 277 (4):307-11

[22] Cf. Hodges MH. History of the TDS medical information system. In: Blum BJ, Duncan K. eds. *A History medical informatics*. New-York : ACM press, 1990, 328-344 .

[23] Data confidentiality and preserving personal privacy is a recurrent ethical issue in healthcare establishments and public administrations generally. (Benson T., Why general practitioners use computers and hospital doctors do not (part 2: scalabilty), in *BMJ*, vol. 325, 9 nov 2002, p. 1092)

[24] *Code de déontologie médicale, op.cit*., article 34

France and abroad. **Arriving at a uniform system for an entire hospital or a group of hospitals is essential.**

- It is a fact that to begin with the system must go through an adjustment phase lasting several years before it can be perfectly suited to patients' needs and that, during the transition phase between manuscript prescription and its electronic counterpart, patients are treated in conditions that can be described as experimental. However, insofar as the software does not abruptly replace handwritten prescriptions and is integrated gradually under the supervision of data processing experts, it would be exaggerated to consider that patients admitted to units engaged in this transition are no more than guinea pigs engaged in technological experimentation.

- It would be contrary to the general philosophy of medicine to condemn out of hand innovations which could reduce prescription writing errors in hospitals simply because such innovation entails a degree of risk that is still difficult to quantify. Even though the regrettable absence of an **"error culture"** in hospitals makes it impossible to even attempt an evaluation pf prescriptive error, it is no secret that error does exist and this is common knowledge in hospital environments[25]. Therapeutic innovation, with its iatrogenic effects and its sometimes invasive characteristics, cannot be viewed in the same light as the traditional model of empirical prescription. That is the reason why, even though it may raise some understandable apprehension because of past events, the concept of "computerised medical prescription writing" reveals a legitimate need to improve prescriptive practices which is far from being specific to France[26]. If practices which are found to be faulty by the very people who use them continue to be applied, progress becomes impossible.

- Very probably, **validation of a computerised prescription writing system** can only be empirical. However, the testimony given by carers who are now familiar with this

[25] Studies published in the United States on this subject give large figures which led to controversy. Between 44,000 and 98,000 Americans die every year as a result of medical error (*Institute of Medicine of the National Academies*, 2000; Thomas, E.J., D.M. Studdert, H.R. Burstin, E.J. Orav, T. Zeena, E.J. Williams, K.M. Howard, P.C. Weiler, and T.A. Brennan. 2000. *Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado*.[Comment]. Medical Care 38 (3):261-71

- Cf. Chassin, M.R. 1997, *Assessing strategies for quality improvement* Health Aff *(*Millwood*)* 16 (3):151-61 "18,000 Americans die each year from heart attacks because they did not receive preventive medications, although they were eligible for them" (cf also Institute of Medicine, 2003a)

- "Medical errors kill more people per year than breast cancer, AIDS, or motor vehicle accidents" *(Institute of Medicine,* 2000; Centers for Disease Control and Prevention; National Center for Health Statistics: Preliminary Data for 1998, 1999)

- "More than 50% of patients with diabetes, hypertension, tobacco addiction, hyperlipidemia, congestive heart failure, asthma, depression and chronic atrial fibrillation are currently managed inadequately" (*Institute of Medicine*, 2003c; Clark et al., 2000; Joint National Committee on Prevention, 1997; Legorreta et al., 2000; McBride et al., 1998; Ni et al., 1998; Perez-Stable and Fuentes-Afflick, 1998; Samsa et al., 2000; Young et al., 2001) .

[26] Donald M., Berwick, M.D., "Errors Today and Errors Tomorrow", *The New England Journal of Medicine*, 348; 19/06/ 2003 : "If the Institute of Medicine is right, then at the very least, 100 patients will die in hospitals in the United States today because of injuries from their care, not from their diseases. How many will die tomorrow? (…) Left alone, systems tend to deteriorate.

tool, and who find it very astonishing that in this day and age people persist in prescribing and administering treatment on the hazardous basis of scribbled sheets of paper, featuring deletions, alterations and omissions, is surely worth listening to. The principle of precaution which proscribes proposed action if it introduces a potentially serious and irreversible risk would not be applicable since several ongoing experiments in various French healthcare institutions have been well received by users, despite technical problems and constraints connected to handling the tool. Albeit still fairly sparse, there is authentic interest in the medical world for this kind of technological tool. In view of the difficulties which are frequently encountered, users who feel motivated to use such an instrument are developing what Ferrera would call "compensation strategies"[27]. The interest made clear by the perseverance of some teams should be accurately evaluated so as to be able to respond usefully to the preoccupations — which are very understandable — generated by these tools in the minds of those who are more reluctant.

- It should not be forgotten that the **computerised system** will never be more than one component amongst others within a healthcaring environment in which **speech must remain the predominant mode** of relating with patients. It would be a pity if the healthcaring quality of a hospital were to be evaluated according to its degree of technological sophistication. Although computerised prescription systems are not in themselves a danger and deserve to be extended once they are proven to be satisfactory, it would be superficial to believe that computers alone will reinvest hospitals with solidarity. Transposition of the managerial paradigm to an institution as particular as a hospital can only be applicable up to a certain limit; there is no software that can protect a doctor against prescription error. Computerised prescription must be clearly seen for what it is: **an efficient prescription tool and not a substitute for therapeutic decision.**

- the danger — if there is one — of extending this technological advance to the entire hospital world does not reside in the technical objects themselves. Perhaps more should be feared from the mindset that technological "miracles" may generate: that insidiously comforting thought that everything can be programmed and manipulated to the heart's content. Beyond the specific problem of prescription computerisation, vigilance is of the essence to avoid a situation where not only instruments but also minds, run like machines.

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February 16, 2006

[27] Ferreira M., *Utilité et utilisabilité de l'informatique dans la gestion du travail bancaire, (Use and uses of the computer in the management of banking)* Ecole pratique des hautes études, Paris, 1998

ANNEX:
The Louise Michel Hospital pilot project, Evry

A hospital staff satisfaction survey in 2004 showed that all those involved (medical, paramedical and administrative personnel) were favourably impressed. Healthcarers appreciated the improved legibility (the amount of paper accumulating in manuscript records previously made a complete file difficult to access), more reliable data collection (observation, monitoring, prescriptions, administration of medicines), the accuracy of calculations (severity and nursing load scores, work-ups at admission and when leaving, scores for tariffing purposes), the benefits due to complete traceability of treatment, procedures and documentation including staff identification, the comprehensiveness of data collected (monitoring data acquired every five minutes, totally accurate manually acquired data). Direct improvement of patient management was very clear as regards:

- Extremely helpful diagnosis assistance (patient incident monitoring, detection of nosocomial infections).
- Uniformity in the prescription of treatment and complementary tests.
- Improvement in patient treatment throughout, including prescription, treatment administration and follow-up.

Advantages for the staff are also considerable:

- Elimination of tedious and repetitive tasks (recopying test results, calculation of scores and work-ups, establishment of data required for tariffing).
- Reduction of time required for data acquisition (particularly elimination of the need to recopy data).
- Easier reading of records for healthcarers.
- The requirement for meticulous data acquisition.
- Simplification of the tasks of various categories of personnel (secretarial work putting together medical records, referencing pharmaceutical orders, etc.).

Far from dehumanising the caring relationship, prescription computerisation can even incorporate, as was the case in the previously quoted example, an "ethical data-sheet configuration" which can improve communication with patients and families (recording of empirical information such as the number of telephone calls, of people spoken to, of family members, their attitude to the medical profession, their degree of understanding of information provided). The scope of recordable data is infinitely extensible since there are no limits to storage facility.

To sum up, staff training programmes must help them to become accustomed to three types of tool:

- a bedside data acquisition and display software;
- a tool to configure that software (acquisition and display) to suit each unit;
- software to extract patient data (present or archived).

All applications can be developed with the combined use of these three tools.