Editorial

Recommendations of the Assistance Publique des Hopitaux de Paris, AP-HP (Paris Public Hospitals Group) France: *The role of medical and non-medical staff in providing information to patients*

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Summary

The 20 key points of the AP-HP document (Assistance Publique des Hopitaux de Paris)

1) Hospital doctors must provide health care recipients with information in compliance with standards laid down by the medical code of ethics.

2) Radiographers and nursing staff must contribute to the provision of information within the framework of their assigned responsibilities and in compliance with their professional rules.

3) Doctors must draft prescriptions clearly, ensure that the patient and immediate family circle understand them and encourage compliance.

4) Doctors have a duty when examining, treating or advising to provide clear, appropriate and fair information regarding the patient's condition and the investigations and treatment proposed. During the course of the illness, physicians must take into account their patients' individual personalities when providing explanation and ensure these are understood.

5) Unless the condition places others at risk, a particularly grave diagnosis or prognosis may be withheld from a patient if the doctor, in good faith and for legitimate reasons, believes this to be in the best interests of the patient.

6) A patient should be informed of a fatal illness only after due consideration by the physician. Close relatives must always be informed, however, unless the patient has previously forbidden this or designated third parties to impart the information.

7) When several doctors collaborate on a di-

*) Report drafted in French 11/07/2000 by the "Hospital Practice and Accreditation" Sub-committee of the Hospital Medical Commission (CME) by Prof. P. Legmann, Radiology representative at the CME, and subsequently circulated to AP-HP radiologists. The recommendations were taking into account written regulations, codes of ethics, the role of radiographers and nurses in informing patients and legal opinion published by ANAES (France's National Accreditation and Health Care Evaluation Agency) (3) and the French National Advisory Committee on Ethics (Comité Consultatif National d'Ethique).

agnostic or treatment procedure, they must keep each other updated on the case. Each practitioner shall assume personal responsibility and inform the patient within the realm of his/her competence.

8) Oral information is priority and must be clear, fair, understandable and ordered.

9) The duty to inform is continuous. Consistent and constant information must be provided at all stages and, where possible, by the same physician.

10) Information must be provided on the benefits expected from a procedure and possible serious attendant risks, however exceptional.

11) Where possible, the practitioner should always verify that the information imparted has been properly understood.

12) It is recommended that:

– hospital doctors accompany oral information with printed leaflets where these aid understanding;

– departments set down a list of those invasive procedures requiring information leaflets. This practice will also help to standardise presentation of the risks and benefits.

13) Patients should not be requested to sign information sheets.

14) It is recommended that for each patient, one member of the medical team be designated, with responsibility for informing the patient and close relatives.

15) On patient admission, details of the family members to be informed must be systematically collected. Similarly, parents or guardians must be systematically contacted on the admission of children.

16) What information is to be given the patient and close family must be discussed by the medical group and the decisions taken recorded in the patient's file.

17) Each department shall define rules on giving information over the telephone to the family or immediate circle. These rules must be set down in writing and understood by all staff concerned.

18) Any information given to the patient must be noted in the medical file. It is to be presumed that only the details noted have been communicated. In this way, the patients' medical record serves as a communication tool for the various members of the medical team regarding the information given to the patient.

19) Obtaining written patient consent (permission to operate and similar documents) is neither compulsory nor recommended, except where required by law. The law demands that written consent be obtained for the following: biomedical research, fertility treatment, termination of pregnancy, genetic research, harvesting of organs from a living donor, certain organ harvesting from a deceased person, surgical procedures on a child.

20) In the event of litigation centring around failure to inform, no evidence, not even written evidence, is a watertight guarantee that the doctor has fulfilled his obligation. Whether information has been correctly imparted or not will be assessed on the basis of a range of elements such as: the period allowed the patient to take an informed decision, the number of visits, practitioners consulted before proceeding, the systematic provision of information leaflets and the notes made on the patient record.

General principles

Informing patients is a professional and ethical rather than legal matter. It becomes a legal issue only if any failure to inform has serious consequences for society or the individual.

The following recommendations on provision of information are to be viewed in this context.

The size and health care capability of AP-HP (Annex 1) and the recent reclassification of heath care systems in the world (Annex 2), make the AP-HP recommendations an interesting reference document.

Failure to inform is often alleged by patients bringing charges. A recent opinion issued on January 5, 2000 by the *Conseil d'Etat* (Council of State) and a decision by France's supreme court, the *Cour de Cassation*, have ruled that before undergoing a procedure or treatment, patients must be informed only of the most frequently observed complications arising from that treatment or procedure. "Refusal of the patient to be informed", "emergency situations or impossibility to inform" are instances where this duty to inform is waived. While the physician is obliged to prove that information has been delivered, recent decisions have confirmed that doctors are not obliged to indicate all attendant risks to their patients. In addition, there is no requirement to obtain signed con-

sent from the patient, any such document having scant legal value. Preferably, information should be given orally, and the fact that the patient has been informed noted on the clinical record. The duty to inform is continuous throughout the health care process. Information leaflets explaining diagnostic procedures to patients are considered useful, provided accessible language is used to describe the pathology and its risks, diagnostic or therapeutic procedures and possible alternative treatments. All information must be validated against the most recent data in the literature. Patients should not be requested to sign these information sheets. Authorisation to operate is required by law only in the case of children. As the hospital setting is characterised by a large range of different care providers, it is all important to ascertain who is responsible for informing the patient. Each specialist should impart general information on his/her field of activity. All information must be consistent with that given by fellow practitioners. The attending physician must ensure that the patient is provided general information. He/she is also responsible for circulating information to colleagues. The patient's clinical record or file should have a section summarising the main information given.

Physicians must ensure that information is simple, accessible, intelligible, fair and understandable. A patient should be informed of a fatal illness only after due consideration by the attending physician. Close relatives should always be informed, however. Unless a person is suffering from a condition which could place others at risk, a particularly grave diagnosis or prognosis may be withheld from a patient if the doctor, in good faith and for legitimate reasons, believes this to be in the best interests of the patient. When several physicians collaborate on diagnostic or treatment procedures, each practitioner shall assume personal responsibility and inform the patient to the extent of his area of competence. Non-medical staff (radiographers and nurses) are also held, within the limits of their remit, to inform persons in care. Rules must be established regarding information to be given over the telephone. Documents proving patient consent are not compulsory. In the event of litigation, it will be a series of indications (medical reports, time allowed patients to come to a decision, referral to specialist opinion, etc.) that will indicate whether the medical practitioner has fulfilled the duty to inform. Appropriate information must be given patients undergoing a technical procedure both before and during the procedure itself. Operators in radiology departments must ensure the patient is made to feel at ease and given appropriate information during the investigation or therapy session. Specific provisions govern information in areas like genetics, biomedical research, termination of pregnancy, fertility-drug treatment and organ harvesting from technically living patients.

Patient information requirements for practitioners operating in imaging departments

Patients undergoing radiological diagnostic investigation must be informed of the reasons for the examination and the risks entailed. Any alternative procedures should be presented, if such procedures are readily available and afford less patient discomfort.

Aids to information

While oral information should be privileged, the explanation of imaging and other technical procedures is facilitated by back-up written information. This should take the form of:

- explanatory posters displayed in waiting and changing rooms;
- information sheets handed to patients explaining the procedure and the degree of patient co-operation expected.

Video cassettes and closed-circuit television may also be used to provide useful supplementary information. Such information aids are often appropriate for patients under stress, with poor eyesight or unable to read without spectacles, as well as for illiterate or non-French speaking patients.

Information on application for the investigation

Radiological investigation is now defined in terms of demand rather than prescription,

since it is the radiologist who is best able to judge the risk-benefits and hence suitability of an investigation requested by an attending physician. Indeed, it is within the radiologist's remit to refuse a request is he/she thinks fit.

Since the decision to conduct radiological procedures involves two practitioners – clinician and radiologist – the duty to inform is shared by both. In order for the patient to avail himself of the right to accept or refuse a procedure, sufficient time must be allowed him/her to assess the potential risks and benefits. (This does not apply in an emergency situation.) The patient must therefore receive information from the requesting physician when the procedure is first proposed. Providing information to the patient only on arrival at the Radiology Department for the investigation is an unacceptable practice, especially since patients are generally unaware or underestimate the risks associated with diagnostic imaging techniques. Like the requesting physician, the radiologist also has a duty to inform. In order to ensure satisfactory information provision, the radiologist must, on the basis of the information received from the referring physician, assess whether the investigation requested is justified and if so, ensure that the patient is informed and follows any preparatory advice (fasting, withdrawal of certain treatment regimens, blood creatinine assays, etc.).

On making the appointment, the radiologist must ascertain the patient's understanding of the procedure envisaged and collect sufficient information in order to guarantee appropriate care provision. This two-way information flow must be an integral part of all provision of care.

Recording the information given

Keeping a trace of the information given the patient by the radiologist presents practical difficulties on account of busy department schedules, the absence of a radiological clinical chart and especially, the real difficulty of getting the patient's clinical record transferred to the radiology department for very short periods.

The Committee recommends therefore that:

- for procedures presenting special risks, appropriate information sheets be systematically handed out to all patients;
- all information given be indicated on the patient's clinical record when this is available;
- the type of information given the patient be indicated on the radiology report; the patient should be told that this record has been made.

The *Recommended Procedures* based on "Patient Information in Radiology" published by the French Society of Radiology in 1999, make a distinction between information regarding diagnostic and interventional radiological procedures.

a) Information to be given patients prior to non-interventional radiology should:

– describe the procedure itself and state the risks attached to the injection of contrast medium;

– make clear that some procedures, while not requiring contrast medium or particular preparatory measures, nonetheless expose the patient to X rays (conventional radiography, scans not requiring contrast medium) or to a powerful magnetic field (MRI).

Routine procedures are conducted by radiographers. It is part of their remit to provide patients with appropriate information on the practical aspects of the investigation or treatment. The patient must be also made aware, however, that the radiologist is available to answer specific questions. If the radiologist meets the patient only at a later stage in the process, the referring physician should have provided the patient with sufficient initial information. It is recommended that the radiology department ascertain whether in fact patients have been told of what the procedure entails.

As well as information sheets, wall posters or video-cassettes displayed and shown in changing rooms and waiting rooms are useful. Information should include contraindications to MRI, the recommendation to ensure high fluid intake after injection of iodine contrast medium (except for those on special diets), radiation risks, etc.

Women of child-bearing age should be systematically informed of radiation hazards during pregnancy. This should be done both when the appointment is made as well as on arrival at the radiology department. A series of routine questions to female patients at potential risk should be envisaged.

b) Informing the patient prior to interventional (invasive) radiological procedures performed under anaesthetic.

These limited but high-risk procedures require the same approach as surgery, especially since today interventional radiology constitutes an alternative to surgery.

A preliminary interview with the radiology specialist is therefore necessary and with the anaesthetist if anaesthesia is to be performed. It is recommended that a report of the interview be given or sent to the patient, physician and referring doctor.

The radiologist should always take the precaution of ensuring that the patient has been made aware of the aims of any diagnostic procedure to be carried out. Experience shows that patients are often not told of these aims. The radiologist should therefore not take for granted that other practitioners (e.g. the requesting physician) have provided this information.

Explanation should focus on how the investigation fits into the overall care management programme and address three main areas:

1) the pertinence of the investigation in light of the patient's condition and its future outcome;

2) the exact nature of the procedure proposed and its consequences – over and above the risks, any existing diagnostic or therapeutic alternatives and other features such as local or general anaesthesia, whether an out-patient procedure, etc.;

3) the risks involved.

The radiologist must be aware that the information he/she provides will be key for the patient – especially on subsequent reflection – since no one expects practitioners in other fields to have the same in-depth knowledge of radiological procedures as the practising radiologist.

The patient must be reassured, but at the same time made to understand that where a surgical alternative exists, no procedure involving anaesthesia, be it surgery or interventional radiology, carries "zero risk".

The radiologist must inform the patient that he/she will be seen by the anaesthetist.

The radiologist must, however, ensure that the patient has been informed of the anaesthesia procedure.

The specificity and complex nature of these procedures mandate that the task of informing the patient be conducted personally by the radiologist and not delegated to non-medical personnel.

After the procedure, the patient must be seen every day until discharge. After every visit, patient progress must be noted in the patient's clinical file. Radiologist physicians are encouraged to provide patients a full report of the procedure and post-operative course, inviting the patient to present in the event of problems. The following wording is suggested: "if in the days following the procedure you have experienced difficulties not indicated in this report, please let me know without delay (telephone:)". The patient must return for a check-up, where possible the appointment being fixed prior to discharge. The patient's clinical file should include all data considered when taking management decisions, copies of any correspondence exchanged with colleagues during the diagnostic and treatment process and follow-up, as well as indication of the information given to the patient and/or relatives.

ANNEX 1

The AP-HP group is a public health teaching hospital and a research facility. It is the name given to a group of:

41 hospitals or hospital groups, 878 hospital departments, 25,841 beds.

Each year it handles:

994,600 admissions, more than 880,000 emergency admissions (1 every 35 seconds), 4,845,300 consultations, 32,357 births, 1,581 organ transplants.

The group employs:

71,246 non-medical staff: 61% auxiliary nursing and social assistance staff, 11% clerical employees, 7% technical and manual staff, 6% medical-technical personnel.

It employs 17,859 doctors: 3,036 practising clinicians with university teaching posts, 2,077 full-time physicians, 7,353 part time physicians, 2,045 residents and interns, 3,116 students.

ANNEX 2

World Health Organisation Classification of the health systems of 191 UN member countries

22.06.2000 - Le Monde - Jean Yves NAU

"On Wednesday, June 21 2000, the World Health Organisation (WHO) announced in Geneva the results of an original study aimed

at classifying the health systems of the 191 member countries of the United Nations according to a five-parameter (or performance indicator) assessment system.

Unlike previous studies conducted in recent years on the same subject, the group of WHO experts, headed by Doctors Philip Musgrove, Julio Frenck and Christopher Murray, have assessed the general level of health of the population drawing on data from diverse sources such as life expectancy figures, but also the health disparities observed within a given national population, the overall 'reactivity' of the health care system – a parameter derived from the degree of satisfaction of health care recipients and the good working of the system – as well as health care cost allocation among the general population. The study compares each system to what the experts consider the maximum achievable by that country given its resource availability.

This approach, says WHO, has never been applied before to international comparisons of heath care systems. 'We have created a new instrument for measuring health care performance', explains Doctor Murray. 'In the future when this tool has been perfected and we have improved the raw data used for our assessments, we believe this will be an increasingly important tool to help governments improve their heath care systems'.

The results are certainly surprising, not least for the very poor showing of the United States, in 34th position despite the fact that private medicine accounts for some 56% of health care expenditure as against an average 25% in the other industrialised countries (It is 80% in India).

Overall, France heads the field in health care, followed by Italy. European Union countries are all in the top group, with Spain in 7th place, Austria 9th, Greece 14th, UK 18th and Denmark 34th. Contrary to common belief, Switzerland ranks only 20th while Singapore is placed 6th. The performance of the African countries confirms the latest epidemiological data showing the extent to which this continent is afflicted by AIDS and malaria. In fact, Sierra Leone is bottom of the WHO classification after Burma, Central African Republic, Democratic Republic of Congo (former Zaire), Nigeria, Liberia, Malawi, Mozambique, Lesotho, Zambia, Angola, Ethiopia, Somalia, Chad, Swaziland, Guinea-Bissau, while South Africa ranks 164th.

The WHO underlines several serious anomalies in the health care systems of its member countries. One of these is the unregulated permission given to certain public sector practitioners to work in the private sector, described by the WHO as a health care 'black market' driven by inefficiencies in the public systems where health care providers are poorly paid.

The UN organisation has several suggestions for improving the efficiency of health care, first among them 'prepayment of heath care' in the form of taxes, subscriptions to health insurance schemes or social security systems. 'In several countries where the safety net of public health insurance does not exist, numerous families have to pay more than 100% of their income for emergency health care. In other words, 'sickness means debts', the report concludes. As a rule of thumb, the WHO estimates that any country investing less than 60 dollars per person per year on health is depriving its people of access to good health care provision".

ANNEX 3

The Recommendations of ANAES

(27/04/2000)

(Agence Nationale pour l'Accréditation et l'Evaluation en Santé)

I) INTRODUCTION

The recommendations are intended as a guide for physicians on how to provide patients in care with good, relevant and constant information while respecting the specific personality of each individual.

The physician should inform the patient of his state of health, describe the nature of the treatment proposed and the procedures involved, therefore enabling the patient to take informed decisions on whether to accept or refuse the diagnostic and/or treatment procedures.

Information is key for any doctor-patient relationship based on trust. It also allows the pa-

tient to be an active participant in the health care process.

The following recommendations aim to allow the doctor to meet his obligation to inform in compliance with his/her professional code of ethics and the legal provisions safeguarding patients' rights.

The recommendations give indications on the content and quality of information to be imparted, its delivery, consistency, the quality of written documents and the criteria used to assess the quality of the information provided.

The question of proof that information has been supplied is deliberately not dealt with.

Similarly no mention is made of the specific circumstances (children or incompetent adults) in which information must comply with specific legal requirements.

Finally, these recommendations do not deal with those cases in which information cannot be given, either due to the special circumstances or because the patient does not wish to receive information.

II) THE CONTENT AND QUALITY OF INFORMATION

Information shall concern the patient's state of health and the care provision envisaged, be this an isolated procedure or part of a longer period of care. Information must be provided at all stages of patient care.

As well as providing answers to specific questions raised by the patient, information must be imparted taking into account the particular situation of each patient. The information provided must include general and specific elements such as:

1) the patient's condition and the probable course. This requires explanations regarding the disease or pathologic condition and its usual outcome with and without treatment;

2) a description of the examinations, investigations, treatment and other procedures envisaged and their alternatives;

3) their aim, usefulness and benefits;

4) the consequences and drawbacks;

5) the complications and possible risks, even if exceptional;

6) general and specific precautions to be taken.

Regardless of whether information is given orally or with the aid of a written document, the same quality criteria must be ensured. Information must:

1) be well structured, consequential and based on validated data;

2) present the benefits to be expected from the treatment and the drawbacks and possible risks, specifying any serious risks, even if these are infrequent, i.e. life-threatening risks or impairment of vital bodily functions,

3) be understandable;

4) be validated by, for example, groups of experts on the basis of recognised criteria (e.g. quality criteria underpinning the professional recommendations adopted by ANAES).

The physician must at all stages ensure that the patient has understood the information given. The reasons for all medical decisions must always be given.

III) HOW TO INFORM

III.1) Priority to oral information

As information implies dialogue, it should be given orally.

Oral information may also be adapted to suit individual personalities. Time must be set aside for informing patients, and information should be given in the manner best suited to the particular situation. The environment must be appropriate. Informing a patient is part of a person-to-person relationship and as such involves listening and understanding. Information may have to be given in a gradual fashion.

Informing a foreign patient may require the services of an interpreter.

Any exchange regarding the risks and benefits of the diagnostic and therapeutic strategy should be noted on the patient's clinical record before an invasive procedure is performed.

All written documents must indicate whether the patient has been invited to ask questions.

It is recommended that information sheets be prepared in the main foreign languages spoken in France.

Video or multi-media supports are useful supplements to oral and written information. These information tools must comply with the same quality requirements as written documents.

IV) ASSESSING THE INFORMATION PROVIDED

All information given to patients should be assessed.

IV.1) Patient satisfaction should be assessed

Patient satisfaction with the oral or written information provided must be evaluated. Patient responses must be borne in mind when updating existing documents or developing new ones.

IV.2) Informing capability

Regular monitoring of how information is imparted. This should entail:

- surveys among patients on whether and how information has been provided;
- retrospective analysis of medical reports to assess – among other things – what information has been provided the patient.

IV.3) The quality of written documents.

The following should be assessed:

- drafting method, namely the method used to assess understanding of the document by non doctors, as well as the scientific exactness of the information provided;
- the information source, i.e. expert groups, hospitals etc. and the date of the information.

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