

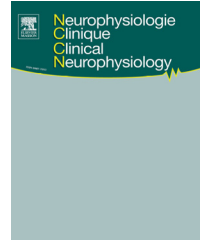


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ORIGINAL ARTICLE/ARTICLE ORIGINAL

Tele-transmission of EEG recordings



Télétransmission des électroencéphalogrammes

M. Lemesle^{a,*}, N. Kubis^{b,c}, P. Sauleau^{d,e}, S. N'Guyen The Tich^{f,g},
A. Touzery-de Villepin^h

^a Service de neurophysiologie clinique, CHU de Dijon, 1, boulevard Jeanne-d'Arc, BP 77908, 21079 Dijon cedex, France

^b Service de physiologie clinique-explorations fonctionnelles, université Paris Diderot, Sorbonne Paris Cité, hôpital Lariboisière, AP-HP, 2, rue Ambroise-Paré, 75010 Paris, France

^c Unité Inserm 965/Paris 7, angiogenèse et recherche translationnelle, hôpital Lariboisière, 2, rue Ambroise-Paré, 75475 Paris cedex 10, France

^d EA 4712 « comportement et noyaux gris centraux », université de Rennes 1, faculté de médecine, avenue Léon-Bernard, 35043 Rennes, France

^e Unité des explorations fonctionnelles neurologiques, CHU de Rennes, 2, rue Henri-le-Guilloux, 35033 Rennes, cedex 9, France

^f Unité de neurologie pédiatrique, CHU d'Angers, 4, rue Larrey, 49100 Angers, France

^g LARIS EA 7315, LUNAM, université d'Angers, 4, boulevard Lavoisier, 49016 Angers, France

^h Unité de neurophysiologie clinique de l'enfant, hôpital Arnaud-de-Villeneuve, 34295 Montpellier, France

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Summary EEG recordings can be sent for remote interpretation. This article aims to define the tele-EEG procedures and technical guidelines. Tele-EEG is a complete medical act that needs to be carried out with the same quality requirements as a local one in terms of indications, formulation of the medical request and medical interpretation. It adheres to the same quality requirements for its human resources and materials. It must be part of a medical organization (technical and medical network) and follow all rules and guidelines of good medical practices. The financial model of this organization must include costs related to performing the EEG recording, operating and maintenance of the tele-EEG network and medical fees of the physician interpreting the EEG recording. Implementing this organization must be detailed in a convention between all parties involved: physicians, management of the healthcare structure, and the

Abbreviations: EEG, Electroencephalogram; Tele-EEG, Electronic transmission of EEG for remote interpretation.

* Corresponding author. Service de neurophysiologie clinique, CHU de Dijon, 1, boulevard Jeanne-d'Arc, BP 77908, 21079 Dijon cedex, France.

E-mail address: martine.lemesle@wanadoo.fr (M. Lemesle).

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company providing the tele-EEG service. This convention will set rules for network operation and finance, and also the continuous training of all staff members. The tele-EEG system must respect all rules for safety and confidentiality, and ensure the traceability and storing of all requests and reports. Under these conditions, tele-EEG can optimize the use of human resources and competencies in its zone of utilization and enhance the organization of care management.
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MOTS CLÉS

Recommandations ;
Electroencéphalogramme ;
Télé médecine ;
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Résumé Les électroencéphalogrammes (EEG) sont télétransmissibles et interprétables à distance. Ce document vise à définir le cadre d'utilisation et de réalisation de la télé médecine en EEG. L'acte de télé-EEG est un acte médical à part entière qui répond aux mêmes exigences de qualité qu'un examen interprété localement, tant sur les indications, la formulation de la demande médicale que sur l'interprétation médicale fournie. Il est soumis aux mêmes obligations de moyens et de qualité. Il doit s'inscrire dans une organisation médicale (« un réseau médico-technique ») et suivre toutes les règles et les recommandations de bonnes pratiques. Cette organisation doit faire l'objet d'un modèle médico-économique associant couverture des frais de réalisation de l'enregistrement, du fonctionnement du réseau de télétransmission et la rémunération du médecin neurophysiologiste interprétant l'enregistrement. La mise en œuvre de cette organisation doit faire l'objet d'une convention entre toutes les parties concernées : médecins, directions des établissements de santé, prestataires de télétransmission. Cette convention a pour objet de fixer les règles de fonctionnement, de financement et de formation continue des partenaires. Le dispositif de télétransmission des EEG doit respecter les règles de sécurité et de confidentialité, la traçabilité et l'archivage des demandes et des comptes-rendus. Sous réserve du respect de ces règles, la télé médecine en EEG permettra d'optimiser l'utilisation des ressources humaines et des compétences sur son périmètre d'application et permettra d'optimiser l'organisation des soins médicaux.
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Summary of guidelines

Tele-EEG is a complete medical examination that upholds the same quality criteria as a test performed in a local setting, in terms of indications, writing the medical request and interpretation.

The implementation of a tele-EEG service must be defined by an agreement between all relevant parties: physicians, managing entities of the healthcare centers, and the company providing the tele-EEG service.

The implementation of a tele-EEG service should be validated with a signed contract from the relevant health authorities.

In the telemedicine framework, the partnering hospitals or centers need to meet all the necessary medicolegal obligations as well as those pertaining to use of digital data.

The objective of tele-EEG service contract is to set guidelines for the functioning, financing and continuous training of all partners.

Within this tele-EEG contractual agreement, the technician and physician from the requesting center must:

- validate the absence of contraindications to EEG activation procedures (e.g. intermittent photic stimulation, hyperventilation);
- collect all clinical data concerning the patient;
- when possible, the physician should obtain informed consent from patients for the telemetric transmission of its EEG.

The EEG recording execution is under the responsibility of the physician and medico-technical team of the requesting center and should respect the recommendations for standard EEGs.

EEG recording procedures must be validated in a written document developed with the neurophysiologist(s) interpreting the EEGs; these procedures should be regularly updated.

Sending the EEG recording is the responsibility of the medical/technical team at the requesting site.

The file sent for interpretation must be associated with the EEG trace and precisely include the following elements:

- full name and telephone number of the requesting physician who is clinically responsible for the patient;
- full name and telephone number of the healthcare professional who performed the EEG and is aware of the recording settings;
- all clinical data necessary for the proper interpretation of the recordings.

All medical, administrative and EEG data concerning the patient are electronically transmitted according to safety and confidentiality guidelines abiding by standards set for health-related data.

In an emergency context, the requesting physician must inform by all means (phone, fax, email) the interpreting-center that an EEG recording is incoming.

The interpretation of the EEG recording, edition and transmission of the medical report are the only responsibilities of the interpreting physician.

The requesting center is in charge of receiving the report and delivering it to the prescribing physician.

The requesting center is responsible for the use of the information contained in the report transmitted by the interpreting physician.

The mention that the EEG was interpreted at a distance must be noted on the patient's medical record and on the EEG report.

The data exchange platforms must ensure strict medical confidentiality, traceability of the exchanges (transmission logs) and the storage of EEG requests and interpretation reports.

The EEG recordings are sent in a compatible format previously determined by both the requesting and interpreting centers.

The EEG and its report will be stored by the requesting center according to the law on storage of medical records.

The organizations belonging to this tele-EEG network ensure the implementation, management and administration of the network, technical updates and evaluation of operating performances.

If neurophysiologists in charge of interpreting the EEG judge that they do not have enough data, or that the quality of the recording is insufficient, they can request an additional recording and/or not provide a conclusion for their report, while explaining their decision in writing on the network data exchange platform.

The requesting and interpreting centers must have an operational access to the electronic transmission network.

There must be a signed maintenance contract mentioning the company in charge of repairing the system and the delay needed for the system to be fully functional again in case of technical difficulties.

A procedure must be implemented in order to overcome any dysfunctions in case of emergency.

This procedure should be integrated within the agreement signed by all parties.

Full-length guidelines

The text below is based on the following references:

- Décret n° 2010-1229 du 19 octobre 2010 relatif à la télémédecine. JORF n° 0245 du 21 octobre 2010. Legifrance.
- Circulaire N° DGOS/PF3/2012/114 du 13 mars 2012 relative au guide méthodologique pour l'élaboration des contrats et des conventions en télémédecine. Ministère du travail, de l'emploi et de la santé.
- Guide méthodologique pour l'élaboration des contrats et des conventions en télémédecine. Direction générale de l'offre de soins (DGOS).

- Le cadre légal de l'échange et du partage des données de santé. Journée régionale des systèmes d'information de santé. Blois, 12 janvier 2012, Jeanne BOSSI, secrétaire générale de l'ASIP Santé.
- La télémédecine en action. Vingt-cinq projets passés à la loupe. Un éclairage pour le déploiement national. Tome 1 : Les grands enseignements. ANAP, mai 2012.
- La télémédecine en action. Vingt-cinq projets passés à la loupe. Un éclairage pour le déploiement national. Tome 2 : monographies. ANAP, mai 2012.
- Cadre d'interopérabilité des systèmes d'information de santé (CI-SIS). Référentiels d'interopérabilité. 26 mars 2013. ASIP Santé. Esante.gouv.fr.

Preface

By exploring central nervous system function, EEG is the essential functional complement to imaging exams that provide mostly morphological data. Similarly to radiological examinations, EEG can be sent for remote interpretation.

The objective of this document is to define the use and practices in tele-EEG. It is based on the studies of the G4 workgroup (Société Française de Radiologie)-CNOM-DHOS, the 2009 Telemedicine report from the CNOM, the Professional Code of Ethics in Medicine, the 2012 Telemedicine Report from the DGOS, the "Guide Télémédecine en Actions" (ANAP, May 2012), Methodological guides from the DGOS (elaboration of contracts and conventions in telemedicine/elaboration of the regional program in telemedicine), the document "Télémédecine et Responsabilités Engagées" (DGOS, May 2012) and the document "Cadre Général d'Interopérabilité" (ASIP, version 1.2.0).

Tele-EEG is a complete medical act on its own, with the same quality requirements as a local one, not only for the indications and formulation of the medical request but also for the medical interpretation. It is subjected to the same obligations of means and quality. It must be part of a medical organization ("medico-technical network") headed by a referent neurophysiologist and must abide by all rules and guidelines of good medical practices. As such, it must be financially compensated.

The implementation of a tele-EEG network must be driven by a Charter on the one hand, and a Convention on the other hand:

- the Charter details the ethical, professional ethics and legal principles as well as organization principles ruling the network, and which are applicable to all members;
- the Convention sets in a binding agreement the organizational aspects (identification of a referent or coordinating physician), legal aspects in terms of shared responsibilities, incident management, conciliation procedures and financial aspects (sharing the costs and remuneration) between members of the network. It is recommended to have this convention validated by the directors of the health centers involved, in the framework of a

contract established with the Regional Health Agency (Agence Régionale de Santé [ARS], in France).

This organization should be supported by a medico-economical model to cover the costs of recording execution, tele-EEG network maintenance and remuneration of the neurophysiologist physician who analyzes the recordings.

Tele-EEG can optimize the use of human resources and competences in its application zone: by bringing neurophysiological competencies to patients in areas lacking trained healthcare resources, it facilitates the access to high-quality healthcare and limits transports and useless and costly hospitalizations. Tele-EEG is an integral part of a care management approach: it should not replace, without a valid reason, local neurophysiological care by a physician with the required competencies and expertise.

State of the art

Data from the literature are quite scarce and concern a limited number of subjects. They are observational studies, reports presenting a local organization and personal experiences from pioneering teams in the field.

Technological advances

The transmission of neurophysiological signals has greatly evolved with the digital age allowing digital transfer of several recording channels, sometimes in real time, due to signal compression without any loss in quality. Transmission time has considerably decreased [8]. These technological advances allowed the development of tele-EEG networks and the diversity of technological solutions is not a limit in itself to tele-EEG [2]. Today, the difficulty remains related to the implementation of these technological systems.

Origin of tele-EEG needs

All aspects of telemedicine can be applied to EEG, especially tele-expertise and tele-diagnosis:

- tele-expertise was first developed in a certain number of countries, in order to help clinicians obtain a second opinion, often part of multi-disciplinary care (care network) for continuous training goals [6]. On a clinical level, this bears several advantages for physicians. Most specifically in epilepsy, tele-EEG provides an undeniable relevance, because of medical issues specific to this pathology and the frequent need to have access to high-level medical expertise. It decreases patients' unnecessary trips to reference centers [4]. This last point is even more relevant for patients in intensive care units, who cannot be moved;
- tele-diagnosis was secondarily developed to interpret examinations in routine clinical practice. Indications are wider than epilepsy and concern all potential EEG indications in most medical specialties. Tele-EEG makes up for the inadequacy between the EEG needs and the number of EEG-competent physicians. As a matter of fact, in France like in most European countries [3], the interpretation of

EEG is confronted with a shortage of competent physicians, especially for the most difficult cases (patients in intensive care, newborns, and premature babies).

Tele-EEG can also be part of tele-assistance clinical care (help in performing a medical act), especially in emergency cases in very isolated or wide territories, like in Russia [9].

Results

Tele-EEG is now a safe, effective and fast technique [3]. The interpretation of tele-EEG recordings vs. standard EEGs has a reliability rate of 92% with a kappa coefficient of 0.87 [7]. It makes up for the absence of competent physicians onsite to interpret the EEG [2,3]. The availability of tele-EEG technique can help better satisfy patients' needs and improve the access to EEG tests by cutting in half the delay in obtaining an appointment [1]. Furthermore, it allows better and more equal access to medical tests and health care.

The organization implemented is appropriate if users are satisfied with good quality examinations and efficient communication between the team performing the EEGs ("requesting center") and the physician interpreting them at a distance ("interpreting center").

Patients' satisfaction

Most patients are very satisfied (99%) and prefer tele-EEG to a traditional specialized consultation [2]. In fact, they have a better access to high-level medical care and save money by avoiding lengthy trips to EEG-interpreting centers. Thus, the patients are spared the average of two hours for having their EEG [2].

Satisfaction of healthcare personnel

This service is also greatly appreciated by medical teams who can use tele-EEG in routine practice and thus offer patients better quality local care [5]. Expert centers offer competencies and in return improve their knowledge on a given pathology by increasing their database [4]. They improve their logistics and data storage capacities. Among other things, it enables teams to conduct cohort studies on important populations of patients, for example, in epilepsy [4].

Cost-benefit analysis

Up to now, no real cost-benefit study has been conducted in France because of the difficulties of defining a medico-economical model for the networks. An Irish study [1] evaluated the unit cost of a tele-EEG at 546€. This study reflects a particular situation, which cannot be generalized, calculating the cost of an EEG test on the basis of a low number of tele-EEG performed (142 tests). Under these circumstances, overhead costs were not covered. Furthermore, this study did not take into account indirect savings (e.g. trips and/or hospitalizations that were avoided, work-days that did not have to be missed) or the global economy in terms of public healthcare and improvement of local quality care.

System set-up and overheads should be profitable because of the advantages provided to patients: less trips

to neurophysiology expert centers, easier verification of the diagnosis and treatment effectiveness, avoiding hospitalizations and quality of life improvement [4]. Local physicians can improve their diagnostic capacities without having a specialized physician onsite. Finally, healthcare providers observe a decrease in global costs, for example, patient transportation and sick days [4].

Guidelines

Based on the above observations, the French experience in tele-EEG and the opinions of the SNCLF workgroup on tele-EEG, which tele-neurophysiology model could we recommend for EEGs?

Guidelines in this document aim to provide a framework for the development of a neurophysiology medico-technical network, and to guide its operations:

- protocols as well as medico-technical, technological, legal, organizational and also financial good practices guides must be written;
- the network must define its status and its legal nature:
 - an ethical charter, signed by any moral or physical entity when joining the network, must list the respective obligations of all network members, especially the obligations of technical and administrative persons in charge of the medical structures involved,
 - rules must be included in the network ethics charter. They detail functioning modalities that might evolve without changing the network's bylaws, especially the network management by a referent or coordinating physician,
 - a partnership convention between the various network members must be signed;
- a medico-technical regional or inter-regional contract must be secured with one or several Regional Health Agencies. This contract should support the network in the framework of a territorial community of hospitals and a contract of means and objectives or a Priority Public Healthcare program (partnership between the neurophysiology medico-technical network and a care center for example).

Medico-technical guidelines

Prerequisite to EEG recording

Like standard EEG, the physician and technician from the requesting center will be in charge of screening for contraindications to certain stimulation modalities during the EEG recording (intermittent photic stimulation, hyperventilation) and the eventual decision to stop these procedures. They also are in charge of administering drugs during the recording, collecting patient's clinical data and obtaining his/her signed informed consent form.

In accordance with legal, ethical and regulatory standards, the information sheet on tele-EEG (Appendix A) and the informed consent form (Appendix B) are collected, each time the patient's condition allows it, by the requesting physician who makes sure that the patient receives complete information on the tele-neurophysiology

procedure and the eventual use of simultaneous video recording (respecting the patient's image rights).

The prescribing physician will have completed a full clinical examination of the patient beforehand and transmitted to the requesting center all clinical data necessary for the proper interpretation of the recordings. These clinical data are formalized in writing and filed in the patient's medical record at the requesting center.

Conducting EEG recordings

EEG recordings are the responsibility of the physician and the medico-technical team or operating team of the requesting center.

The medico-technical team performs the test according to the protocol adapted to the clinical situation as evaluated by the requesting physician. Any EEG recording must adhere to the procedures validated by all healthcare professionals belonging to the network, in accordance with the "French Guidelines on Electroencephalogram" (see the corresponding chapter, NCCN, this issue). If necessary, and in accordance with the neurophysiologist in charge of performing the EEG recording, specific adaptations to the recording procedures can be made.

It is recommended for these procedures to be updated and periodically reviewed by all healthcare professionals involved in the network.

Transmission of EEG recordings

Sending the EEG recording is the sole responsibility of the medico-technical team of the requesting center.

Sending EEG recordings outside of a legal framework predetermined by a convention between centers is exceptional and should not be encouraged.

The file sent for interpretation necessarily includes the following elements that have to be readable and attached to the EEG recording:

- identity and phone number of the prescribing physician. The prescribing physician can secondarily refer his/her patient to the requesting center for the EEG recording, the latter being then tele-transmitted;
- identity and phone number of the requesting clinician in charge of the patient, if he/she is not the one prescribing the EEG test;
- all clinical data needed for the proper interpretation of the recordings. The requesting physician must in fact put down precisely and in writing all details regarding the patient's pathology and the question(s) asked by the prescribing physician.

The elements listed above are compiled into a specific "tele-transmission" electronic form, directly attached to the EEG recording file. On one hand, sending EEG recording alone, without attached information and prescription files is not recommended because it does not offer the same safety and confidentiality guarantees and does not allow the traceability of the requests. On the other hand, sending information and prescription files separately through other means like phone calls, emails, or fax may secure an emergency procedure implemented for a given patient.

The requesting physician is in charge of entering administrative and medical data and then of sending the files via the network. Regardless of the transmission modalities, the EEG recording and attached data files are to be sent by the medico-technical team in strict conformity with transmission protocols and safety and confidentiality guidelines.

Technicians have to make sure that the files transfer is fully achieved. In emergency cases and if the network does not have an automated alert system for the interpreting physician, the medico-technical team has to reach the interpreting physician by all means.

Interpretation of EEG recordings

The interpretation of the EEG recording, the production and transmission of the medical report are the responsibility of the interpreting physician.

The requesting center is then responsible for the future use of the report sent back by the interpreting physician.

In routine tele-diagnosis contexts, outside of emergency cases, the interpreting physician successively connects to the network, downloads the files, analyzes the EEG recording and sends back his/her report to the requesting center.

In emergency tele-diagnosis contexts, the interpreting physician will make sure that the EEG report is correctly receipted and forwarded by the requesting center to the prescribing clinician. If the interpreting neurophysiologists estimate that they do not have enough information, or consider that a recording is of poor quality, they might request an additional recording and/or not send a conclusion with their report, motivating their decision in writing on the network's exchange platform.

The medico-technical staff from the requesting site is in charge of receiving the report and transmitting it to the prescribing physician. The prescribing physician has to be reached at any times, by all means of communication, to receive the conclusion of the interpretation and take the appropriate measures if necessary. The mention "interpretation at a distance of the EEG recording" in the patient's medical record is mandatory. Interpreting centers must make available to requesting centers an agenda for the interpretation of tele-transmitted EEG recordings with a list of phone numbers and times when interpreting physicians can be reached.

Technological guidelines

Since the decree HPST/Telemedicine of October 19, 2010 and the 18-month mandatory delay to conform to standards, data transfer must be handled by a licensed data hosting company.

Data exchange platforms used by both parties must abide by quality and reliability standards: respecting medical secrecy, traceability and storage of requests and reports. These different elements must be highlighted in a convention linking all the network partners:

- recording exchanges between requesting and interpreting centers need a compatible EEG format, this compatibility being predetermined between both partners. Data transfer (EEG and video) acquired by the requesting center must be compatible with reading and analysis software

of the interpreting center. The chosen tele-EEG network must guarantee "a restitutio ad integrum" of the transferred data (notes, video, etc.);

- access to the network must be limited and secure (login/alphanumeric password that must be changed often or, even better, the physician can use his/her Healthcare Professional Card (CPS) to access the system; this card specific to the French system, ensures encrypted data transmission. Secure transfer of all EEG, video, medical and administrative data must abide by the standards applied to healthcare data;
- medical data exchanges (requests and reports) must be stored in a long-term storage system, in order to be kept according to the required legal time (see "French Guidelines on Electroencephalogram"/NCCN, this issue);
 - any data exchange (transferred EEG records and medical data on one hand, and reports on the other hand) must deliver a receipt acknowledgement for all data transmitted and received in order to ensure the traceability of tele-EEG. It belongs to the data hosting company to organize and maintain a transmission log, this log mentioning the origin (transmitter/receiver), situation, date, time and duration of any transmission. All transmitted data (requests for interpretations and reports) must be stored on long-term, secure and non-editable media,
 - the network partners are in charge of the network setup, management, maintenance and updates as well as its medical evaluation (statistics), the role of each being precisely detailed in the agreement. It is very important to regularly update the network practices in order to adapt to technological advances and patients' various healthcare needs.

Legal and organizational guidelines

A network is an organization of healthcare professionals, which is dedicated to optimizing an equal quality healthcare access for all patients in a given region; it provides complementary services to regional health structures in place, and because of that, should be validated by regional authorized health agencies (corresponding to the Agences Régionales de Santé in France).

Regardless of the chosen legal entity, a steering committee and a referent or coordinating physician are in charge of managing the network. They must establish their objectives via a Convention, an Operating Charter with bylaws and good practices protocols. Such a Charter lists ethical obligations, professional ethics rules (abiding by good practices) and legal obligations as well as the network organization principles applicable to all members (eventually detailed in a specific document). Its members, and their medical and non-medical personnel, agree to abide by the terms of the Convention and the Charter. The network's steering committee can decide to exclude a center or a professional that would not respect the rules. The network membership may be individual (physical entity) and/or collective (moral entity). For the patient's benefits, it is mandatory to respect ethical obligations, professional ethics rules, and legal obligations as well as organization rules. A center membership to a tele-neurophysiology network has to be validated by

local authorities (Hospital Administrators, authorized health agencies) and further validated by signing a convention.

The signature of such a convention by the structures' managers is valid for their network members, technicians as well as caregivers. The convention objectives are to set their financial and tele-EEG specific partnership principles. The different partners' obligations are detailed in [Appendix C](#).

Legal responsibility and professional and ethical independence of physicians

Using tele-diagnosis must not influence the professional and ethical independence of physicians. The latter are in charge of diagnosis, therapeutic proposals and chosen decisions. In particular:

- each physician is free or not to use the tele-EEG network and services it offers;
- the interpreting physician may not complete the EEG interpretation if he/she considers that there are not enough data and/or if the recording has technical issues;
- each structure, member of the network, is responsible for the care given by its practitioners to the patients within its premises;
- each physician remains responsible for his/her medical procedures;
- each network is autonomous: each coordinator is in charge of the operating agenda and has the option to close it down in case of dysfunctions, after prior agreement of all concerned network members, according to the modalities defined within their convention.

The use of telemedicine in EEG has to respect the ethical obligations, professional ethics rules and legal obligations as described in regulatory texts (especially articles 4, 5, 12, 32, 33, 36, 45, 60, 64, 69, 72 and 73 from the Code of Medical Ethics), or case-law developments. In particular:

- patients' rights are protected, such as information and consent, quality of healthcare, secrecy of medical data, respect of privacy, free choice of the physician and compensation in case of misconduct;
- the medical practice respects medical ethics in individual practice as well as in relationships with peers: professional independence, medical secrecy and personal responsibility of the physician. The medical team informs the patient or parents in a faithful, clear and appropriate manner;
- network operations require the use of patients' name files. For telemedicine, partnering structures must make the necessary declarations to the structures/governing body in charge of ensuring the personal data protection (corresponding to the Commission Nationale Informatique et Libertés [CNIL], in France).

Financial guidelines

Tele-EEG is not simply the juxtaposition of a technical EEG recording act and the medical act of interpreting. It also includes the entire tele-transmission system. Like any care network, finding proper financing is the guarantee for

long-term telemedicine activity. This financing is dedicated to overhead costs of the tele-EEG network (equipment including network wiring, reading stations and software, servers storing media; and human resources including maintenance and secretarial work for typing reports, coordination, etc.).

Inherent costs to perform the EEG records (i.e. the technical act) are the responsibility of the requesting service. The time required for a physician to interpret these technical acts and provide a report must be clearly identified and financially appraised.

Additional costs for implementing a tele-EEG network might be offset by healthcare savings realized by the country's subsidized government healthcare (corresponding to the *assurance maladie* in France): savings on unnecessary patient transport and/or hospitalizations, reduction in sick days for patients who can have EEG close to their home, improved access to healthcare and improved quality of care in regions where there are not enough physicians and/or specialized centers.

Such a global cost-benefit evaluation has to be conducted, since this is an absolute necessity to balance network additional costs.

Proposals for improving tele-EEG in France

In France, tele-EEG has been used for over 10 years and its reliability and advantages have been validated in routine medical practice as the solution for interpreting, at a distance, technical acts performed close to the patient's home. It gives access to expert competencies and thus constitutes a key solution to the increasing exodus of physicians from certain rural areas.

Guidelines proposed in the previous chapters are the minimum required to be in accordance with the HPST decree/Telemedicine of October 19, 2010 and if possible, to abide by the benchmarks of interoperability of healthcare information systems published by the Agence des Systèmes Informatiques de Santé (technical compatibilities and file exchange formats).

Today's tele-EEG practices in France, having emerged from local pioneering initiatives, are very diverse. A study on the evaluation of these practices jointly initiated by the Société de Neurophysiologie Clinique de Langue Française (SNCLF) and the Ligue Française contre L'épilepsie (LFCE), is underway to evaluate and valorize existing practices and share experiences in order to pool competencies, standardize practices at National and European levels and to lay the foundations for a medical-economic study at a National level.

At the present time, a certain number of proposals can be detailed.

Technological aspects

There is a great variety in EEG data exchange practices everywhere in France, not only from one network to the next but also within a single network, and even within a single University Hospital, from one building to the next and even from one department to the next:

- heterogeneity of recording and reading software (generally related to the various uses and professional objectives);
- heterogeneity of transfer technologies (cables with various speeds; wireless connection with uncertain confidentiality; data transfer by FTP internet server which can be more or less secure and encrypted; even sometimes regular phone line connection by modem).

While several networks have chosen, for simplification purposes, to use only one brand of EEG device in their regional branches ("single-brand" network), others have had to adapt to various requesting centers' choices, often to limit costs, thus generating almost as many types of software and viewers as there are requesting centers.

Evolution towards a common EEG format, allowing cross-reference reading regardless of the brand used, seems to be the best solution to simplify processes and standardize inter-network compatibility, while respecting the diversity of professional practices. European Data Format (EDF) created by a sleep research team in Copenhagen, and EDF+ remains restricted in their use, especially for simultaneous video-EEG recordings.

Standardization and securing of transfer protocols (EEG data encapsulation), such as DICOM used in radiology, are interesting procedures but their implementation remains complex.

Technical improvements can be proposed for operating the tele-EEG network, among them:

- adding an auditory or visual alert system to indicate the urgency of the request, or even better a separate display screen, on the reading panel of the interpreting center, indicating the request nature "planned, urgent or expertise":
 - integrating a system for tracking and verifying the transfer status: on one hand automated receipt/opening/reading acknowledgements from interpreting center (EEG recordings and data files) and, on the other hand, automated receipt and opening/reading acknowledgements from the requesting center (once the sent report has been opened/read);
- some of the data exchange platforms also use this type of system to trace data exchanges and to perform customized activity measures;
- integrating a CPS card reader is recommended to secure authentication of the network's physicians;
- shared storage of EEG recording and video, implying storing voluminous data for a given patient, would enable authorized physicians to access the patient's previous tests performed in one of the network's centers.

Legal and organizational aspects

Tele-EEG can optimize the resources within a regional health community and, through tele-expertise, propose specialized advice in specific areas (e.g. stroke, epilepsy, neonatal care).

Care or medico-technical networks are part of a territorial healthcare organization, the objective being for patients

to have the best access to high-quality care in any part of the country.

Various initiatives from the Ministry of Health have tried to structure these evolutions according to different complementary modalities that could overlap:

- care organization in Communautés Hospitalières de Territoire (CHT), aiming to fulfill the healthcare needs of a population (geographical organization);
- at the regional level, the Regional Telemedicine Program (RTP), listed in the Strategic Regional Health Program (SRHP) for priority healthcare objectives.

A medico-technical network, such as tele-EEG, must be an integral part of a medical project. A state of the art must be conducted at national level to identify the organizations in place, their eventual difficulties and needs.

Generally, we recommend precisely defining the objectives of the network to determine the organization modalities before their legal contraction.

The various partners must define the periodicity for updating the Convention and Charter in a constant effort to keep up with the network's evolution (e.g. new technologies or standards; new members).

Financial aspects

No data are available today in France to evaluate savings in medical time, patient trips to the EEG center, avoided specialized hospitalizations and sick days, or qualitative benefits in the short- and long-term. Tele-EEG financing, regardless of modalities (payment per act, standard costs) must take into account all costs:

- activity-related costs;
- infrastructure-related costs (buying and maintenance of the tele-transmission systems, accounting);
- costs related to computer systems (monitoring of activity, user help-desk);
- costs related to the network itself, quality monitoring, continuous education and training.

To date, no economic study has been conducted in France on existing networks to propose a precise financial model. The need to compensate for the absence of specialists in rural areas should incite the government to promote the various initiatives in this field.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

Appendix A. Patient information form – Model

The objective of tele-transmission of electroencephalograms (EEG) is to have remote interpretation of these tests in order to ensure continuity of care in the absence of EEG board-certified physicians in the establishment where you or your child is hospitalized.

In the framework of the tele-transmission network, data processing of these tests is available. These data are the same which are recorded and stored during your EEG test when interpreted onsite. Data include signals produced by the brain's electrical activity (EEG recording) and a patient's file including identity and medical data needed to interpret the EEG recording. In all cases your identity will only be accessible to the healthcare staff submitted as usually to the obligations derived from the medical secrecy regulations.

If you do not authorize these data to be collected and transmitted to the distant center, we will not be able to perform the EEG.

According to the French Data Protection Act (*Informatique et libertés* – n° 78-17 – January 6, 1978) you can access your personal data at any time and request changes. You can contact the head of the EEG recording site to exert that right. The CNIL (*Commission nationale de l'informatique et des libertés*) is the official body in charge of enforcing this law.

These data are stored according to secure and standardized protocols to ensure full confidentiality and data protection. Only persons subject to medical secrecy obligations and with an authorized access to medical records will have access to computer data via a secure encrypted login and under the responsibility of the person in charge of file management. In case of scientific research, data will be rendered anonymous.

Appendix B. Model of informed consent form for the patient

PATIENT LABEL

I the undersigned:

- Mrs. Ms. Mr.
- LAST NAME.....
- First Name.....

Acting as:

- Adult patient
- Legal guardian of the underage patient

State that I have been informed of the executing of a recording, expertise, ... to be interpreted at a distance in the framework of the xxx network

I agree to have my personal data digitally processed and stored by the xxx network.

I do not agree and will make an appointment with a physician.

These data are collected and digitalized processed according to the amended Law 78-17 from January 6, 1978 relative to computer system, files and personal data.

At any time you will have access to your personal data to amend them or ask for complete removal by writing to

M.....

Address

This document will be kept in your medical records.

Done at.....

Date.....

Read and approved

Signature

Appendix C. Responsibilities of the various telemedicine actors in a tele-EEG network

The medico-technical personnel, e.g. electrophysiology technicians and/or nurses who received specific neurophysiological training, is under the supervision of the Head of the Medical Department or the Person in Charge of the functional unit of the requesting center and the CEO of the organization.

All data acquisition and EEG transmission procedures must be validated by all network members, physicians and technicians. These procedures must be regularly updated, ideally on a yearly basis, and the frequency of these updates will be the object of a convention.

The interpreting neurophysiologist physician and medico-technical staff of the requesting center will have to be trained to use the network(s) implemented in their center. An initial software demonstration session will be organized, and should be repeated annually for newcomers.

The tele-EEG system provider is responsible for abiding by technological standards for tele-transmission modalities, and ensuring sustainability and smooth running of the system. It is also responsible for system maintenance and taking proper actions when needed (24/7).

Requesting and interpreting centers must have an operational access to the tele-transmission network. A maintenance contract mentioning the company in charge of repairing the system in case of dysfunction and the delay needed for the system to be fully functional again must be signed prior to the network implementation. A procedure is needed to overcome system dysfunctions in emergency situations. This procedure must be an integrant part of the Convention signed by all partners.

References

- [1] Breen P, Murphy K, Browne G, Molloy F, Reid V, Doherty C, et al. Formative evaluation of a telemedicine model for delivering clinical neurophysiology services part II: the referring clinician and patient perspective. *BMC Med Inform Decis Mak* 2010;10:49.
- [2] Campos C, Caudevilla E, Alesanco A, Lasierra N, Martinez O, Fernandez J, et al. Setting up a telemedicine service for remote real-time video-EEG consultation in La Rioja (Spain). *Int J Med Inform* 2012;81:404–14.
- [3] Coates S, Clarke A, Davison G, Patterson V. Tele-EEG in the UK: a report of over 1000 patients. *J Telemed Telecare* 2012;18:243–6.

- [4] Elger CE, Burr W. Advances in telecommunications concerning epilepsy. *Epilepsia* 2000;41(Suppl. 5):S9–12.
- [5] Lasierra N, Alesanco A, Campos C, Caudevilla E, Fernandez J, Garcia J. Experience of a real-time tele-EEG service. In: Conference proceedings: annual international conference of the IEEE engineering in medicine and biology society IEEE engineering in medicine and biology society conference 2009. 2009. p. 5211–4.
- [6] Loula P, Rauhala E, Erkinjuntti M, Raty E, Hirvonen K, Hakkinen V. Distributed clinical neurophysiology. *J Telemed Telecare* 1997;3:89–95.
- [7] Nitzkin JL, Zhu N, Marier RL. Reliability of telemedicine examination. *Telemed J* 1997;3:141–57.
- [8] Rozza L, Tonella P, Bertamini C, Orrico D, Antoniol G, Castellaro L. Telephone transmission of 20-channel digital electroencephalogram using lossless data compression. *Telemed J* 1996;2:267–71.
- [9] Uldal SB, Amerkhanov J, Manankova Bye S, Mokeev A, Norum J. A mobile telemedicine unit for emergency and screening purposes: experience from north-west Russia. *J Telemed Telecare* 2004;10:11–5.