

ПРОБЛЕМНІ СТАТТІ

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Model of informed consent for telemedical consultations in Bulgaria

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РЕЗЮМЕ, ABSTRACT

Subjects of teleconsultations may include primary care practitioners / GPs, specialists and subspecialists, residents, medical and technical support personnel. Patients' data (including patient records, medical images, audio and video recordings, output data from medical devices and other) are reserved for medical personnel and may be used in planning and performing diagnostics, treatment, follow-up, teleeducation and scientific research. Patient's confidentiality and identity is protected either by transfer of data that does not identify the patient, or by using network and software security protocols and/or data encryption (Ukr.z.telemed.med.telemat.-2010.-Vol.8,№2.-P.124-127).

Key words: teleconsultation, data protection, ethics

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МОДЕЛЬ ИНФОРМОВАНОЇ ЗГОДИ ДЛЯ ТЕЛЕМЕДИЧНИХ КОНСУЛЬТАЦІЙ У БОЛГАРІЇ

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У процес телеконсультування включаються лікарі загальної практики – сімейної медицини, лікарі-фахівці, інтерни, медичний і технічний персонал. Інформація про пацієнта (текстові записи, медичні зображення, аудіо- і відеозаписи, результати інструментальних обстежень тощо) обробляється медичним персоналом і може бути використана для діагностики, лікування, оцінки наслідків, теленавчання й наукових досліджень. Конфіденційність пацієнта забезпечується або анонімною передачею даних, або програмними та мережевими засобами й протоколами, а також шифруванням даних (Укр.журнал телемедицини та мед.телематики.-2010.-Т.8,№2.-С.124-127).

Ключові слова: телеконсультація, захист даних, етика

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МОДЕЛЬ ИНФОРМИРОВАННОГО СОГЛАСИЯ ДЛЯ ТЕЛЕМЕДИЦИНСКИХ КОНСУЛЬТАЦИЙ В БОЛГАРИИ

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В процесс телеконсультирования включаются врачи общей практики – семейной медицины, врачи-специалисты, интерны, медицинский и технический персонал. Информация о пациенте (текстовые записи, медицинские изображения, аудио- и видеозаписи, результаты инструментальных обследований и т.д.) обрабатывается медицинским персоналом и может быть использована для диагностики, лечения, оценки исходов, телеобучения и научных исследований. Конфиденциальность пациента обеспечивается либо анонимной передачей данных, либо программными и сетевыми средствами и протоколами, а также шифрованием данных (Укр.журнал телемедицины и мед.телематики.-2010.-Т.8,№2.-С.124-127).

Ключевые слова: телеконсультация, защита данных, этика

The practice of telemedicine uses any electronic signal to transmit patients' medical information from one site to another. This includes transmission of medical information and data by video, electronic mail, telephone, and satellite. The benefits of telemedicine are profound. They include:

- improved access to healthcare, e.g., obtaining second opinions;
- improved continuity of care, patient education, and timely treatment, e.g., monitoring the condition of chronically ill patients;
- reduced travel time for physicians, other healthcare providers, and patients;

- better access for patients in underserved areas;
- improved access to medical records and information, e.g., promoting self-help by increasing the online availability of medical information; knowledge-based self-diagnosis programs; distance learning programs; and medical research data/information;
- improved continuing medical education.

Instant access to medical information is beneficial to the medical community. However, this access may jeopardize patient privacy and the confidentiality of sensitive information.

In this case, the patient should declare that he/she understands that he/she has the following rights with respect to telemedicine: 1) He/she has the right to withhold or withdraw consent at any time without affecting his/her right to future care or treatment nor risking the loss or withdrawal of any program benefits to which he/she would otherwise be entitled. 2) The laws that protect the confidentiality of patient's medical information also apply to telemedicine. As such, the information, disclosed during the course of therapy, is generally confidential.

The patient declares that the dissemination of any personally identifiable images or information from the telemedicine interaction to researchers or other entities shall not occur without his/her written consent. In addition, the patient declares that he/she understands that telemedicine based services and care may not be as complete as face-to-face services. Finally, there are potential risks and benefits associated with any form of therapy, and that despite of his/her efforts and medical doctor efforts, the patient's condition may not be improved, and in some cases may even get worse.

The informative declaration should consist of clearly defined possible benefits from telemedicine, but that results cannot be guaranteed or assured.

Telemedical practice includes, but it is not limited to the following potential risks:

- collected and transmitted information may not be sufficient to allow appropriate medical decision making by the physician and consultant(s);
- medical, technical, or other limitations in obtaining, processing, presenting and/or understanding patient data may result in inappropriate decision(s) (e.g. inability to collect all relevant medical information, diagnostic limitations, limited performances of medical devices or computer equipment / available communication

lines, compression or lower resolution of digital images, indirect contact with patient and other reasons);

- delayed evaluation of patient's condition due to failures or deficiencies of equipment may influence the quality of telemedical service;
- prearranged consultants' time schedules and availability may influence time-to-response and decision making;
- patient's condition may vary in time necessary for teleconsultation and relevant (tele)medical procedures;
- in rare instances, telemedical practice algorithms, security protocols and integrity of medical data could be affected or damaged by changes in services, intentional or unintentional actions of any subject involved in teleconsultations (incl. technical support, telecommunication software and hardware providers), or by third parties (hackers, computer viruses), causing a breach of privacy, loss of personal medical information, or other undesirable consequences;
- in rare cases, lack of access to complete medical records may result in adverse drug interactions or allergic reactions, other judgment errors or unexpected medical conditions.

Expected benefits include:

- improved access to health services by enabling a patient to remain in his local doctor's office or at a remote site while the physician obtains consults from healthcare practitioners at distant sites.
- support from distant specialists in multidisciplinary remote diagnostics and follow-up
- medical service for patients isolated by weather and transport conditions
- improved quality and/or frequency of health care, improved cost-effectiveness and time saving
- improved triage or medical management and etc.
- In Bulgarian medical practice there are number of models of informed consent, according to the medical specialty, they are used for: informed consent for childbirth, caesarean section, DNA exam, stem cells, dental treatment, also for the medical treatment. The doctor must inform the patient regarding: 1) his/her condition and need for treatment; 2) disease in respect of which sought health care, and its prognosis; 3) planned preventive diagnostic, therapeutic and rehabilitative activities, and risks associated with them; 4) diagnostic and therapeutic alternatives; 5) name, position and degree of those, involved in diagnostic and therapeutic process. Bulgarian Health Act explicitly states that medi-

cal activities are carried out after obtaining informed consent from the patient.

When the patient is a child or is placed under limited interdiction for carrying out medical activities, it is also necessary an informed consent and the consent of his parent or guardian.

To obtain informed consent, the treating doctor (doctor of dental medicine) informs the patient about: 1) diagnosis and nature of the disease; 2) description of the purpose and nature of treatment, reasonable alternatives, expected results and outlook; 3) potential risks, associated with the proposed diagnostic and therapeutic methods, including side effects and drug reactions, pain and other discomforts; 4) likelihood of a favorable response and health risk, when other methods of treatment are applied or refusing treatment.

Medical information is provided to patients, according to his parent, guardian or custodian

in a timely and appropriate volume and shape, allowing for freedom of choice of treatment.

At surgery, general anesthesia, and other invasive diagnostic and therapeutic methods that lead to an increased risk for patient's life and health or to a temporary change in his mind, the information and provided informed consent can be left out. In this case, the actions can be made to keep the patient's life without written informed consent only when directly is threatened his life.

For persons with mental disorders and inability to express informed consent of the activities that lead to an increased risk for life and health or to a temporary change in his mind, may be made only after authorization by the Committee on Medical Ethics and after taking the consent of their legal representatives or the head of the hospital.

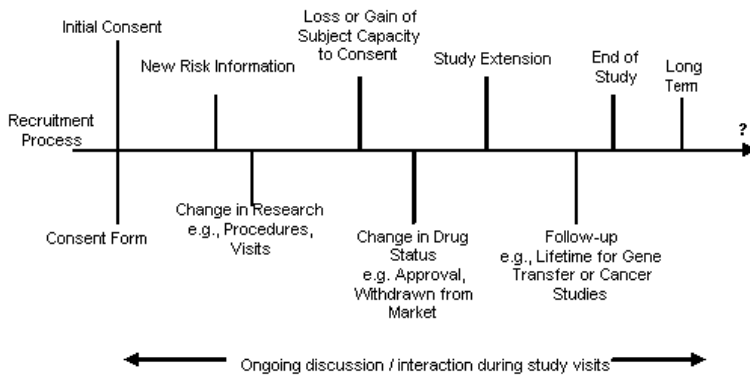


Figure 1. Elements and history line of informed consent [4]

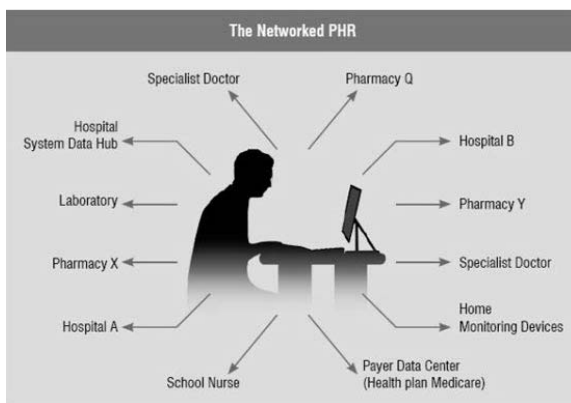


Figure 2. Personal health record content [4]

Patient, respectively, parent, guardian or trustee or a person appointed by the court, may refuse at any time, the proposed medical care or continuing medical activities. Refusal is certified in the medical records with signatures of the person. If the patient respectively his parent, guardian or custodian is unable or refuses to certify the refusal in written form, this is attested by the signature of the physician and witness.

In cases, where there is a refusal by a parent, guardian or custodian, but this endangers the pa-

tient, the head of the hospital may decide to carry out life-saving treatment procedures.

Medical care against the wishes of the patient may be given only in cases determined by law.

Patient access to health information may be limited to written refusal on his part. This decision is pointed in the written medical documentation of the patient. Another specific situation is the clinical trials. They are allowed only to persons who have given their consent after written notification about the nature, importance, scope and potential

risks of testing. Also, each capable Bulgarian citizen and a foreigner, long resident in Republic of Bulgaria is entitled to lifetime explicit written dissent making organs, tissues and cells after death. Expressed disagreement may relate to specific or all organs, tissues and cells, and taking them to other treatments, diagnostic, medical, learning and teaching purposes. The blood donor gives written informed consent and complete declaration for his/her health status. He/she provides information in accessible language for taking blood or blood components to the physiological changes that occur in the body as a consequence, the measures for safety and potential risks. The originals of the documents should be kept by the hospital for a period of 15 years.

Finally, we present author's model of informed consent for telemedical consultation – specific medical service that has no limits and legal rules up to the current moment in Bulgaria.

The author has studied foreign examples and models to develop 2 pages with detailed specific, but not difficult for understanding, information. It is very important to ensure that patient registration information needed by the consulting physician/facility is obtained, in addition to information routinely obtained. The consent ensures that the facility can quickly assemble all components of a patient's record, regardless of their location in the facility. It is defined that the telemedical record media may be hard copy, video- or audiotape, monitor strip, or electronic files.

Информирано съгласие за телемедицински консултации	
Име на пациента:	<p>Чрез подписване на този формуляр аз потвърждавам следното:</p> <p>Аз съм информиран за потенциалните рискове и ползи на телеконсултациите в достоверен и удовлетворителен вид. Телеконсултациите ще бъдат организирани, така че да подобряват управлението на личното ми състояние или за други търсени ползи. Всички аспекти, защитавани и засягани интересите ми при провеждане на телеконсултация са представени и обсъдени обстойно.</p> <p>Знавам си правото да откажа или оттегля съгласието си за провеждане на телемедицински консултации по време на предоставените ми грижи, като това гарантира, че няма да навреди по-нататъшно ми лечение.</p> <p>Съзнавам предоставените ми алтернативни методи на медицинска грижа и съзнавам възможността си да се възползвам от всеки от тях.</p> <p>Разбирам че имам право да проверявам всяка информация, която бъде предоставена в телемедицинската сесия и че имам право на копия от всички материали, произведени по време на провеждането й.</p> <p>Съгласен съм с трансфера на личните ми медицински записи и данни, и предоставяването им на други медицински специалисти в страната или извън нея, с цел постигане максимално удовлетворителна диагноза, по-свободно лечение, телеобразование и трениращи.</p> <p>Осъзнавам, че телемедицинската консултация и по-точно телемедицинското мнение може да бъде нетълно или повредено вследствие на ограничения по независещи от страните фактори.</p> <p>Давам моето информирано съгласие за телемедицински консултации и употреба на Телемедицина при предоставяне на здравни услуги и грижи.</p> <p>Подпис на пациента:</p> <p>(или упълномощено лице, при условие че бъде упомената връзката с пациента и се подпише преди трето лице - свидетел)</p> <p>В гр. _____, дата _____.</p> <p>Имам на разположение копие на настоящия формуляр (инициали на пациента): _____</p>
Дата на раждане:	
Местонахождение на пациента:	
Име на лекуващия лекар (в директен контакт с пациента):	
Степен/ Звание / Специализация:	
Институция:	
Адрес:	
Телеконсултантска болница:	
Информация за пациента:	
Телемедицината включва употреба на медицинска и компютърна апаратура, както и електронни комуникации с цел осигуряване на информация експерти на отдалечено място, трансфер и споделяне на данни за подобряване на пациентското здраве. В телеконсултациите може да вземат участие общопрактикуващи лекари, специалисти, друг медицински персонал.	
Данните на пациента (в това число възраст, пол и инициали, описателни записки на състоянието, медицински изображения, резултати от изследвания и др.) могат да си използват за целите на планиране и предоставяне на диагностика и лечение, телеобразование и специфични научно-исследователски нужди на медицинските заведения.	
Конфиденциалността на пациентските данни е защитена при трансфера си, тъй като НЕ се идентифицира пациента.	
Очаквани ползи:	
• подобрен достъп до здравни услуги, чрез предоставяне възможност за второ експертно мнение	
• медицински услуги за пациенти в неравностойно състояние и местонахождение	
• повишено качество и честота на прилаганите профилактични и превантивни медицински услуги	
Възможни рискове:	
Телемедицинската практика включва, без да налага ограничения, следните потенциални рискови фактори:	
• събраната и предоставена медицинска информация да е недостатъчна за вземане на решение от страна на консултиращия експерт от разстояние;	
• наличие на медицински, технически или други ограничения при получаване, разчитане и разбиране на медицинските данни, което да рефлектира на некоректна диагноза	
• закъснение при предоставяне на телемедицинската консултация по независещи от страните фактори	
• възможност от вариации и промени на пациентското състояние във времевия период между телеконсултациите и наложителните вследствие процедури и схеми на лечение	

Figure 3. Authors model of telemedical informed consent for Bulgarian medical practice

Conclusion

The telemedical declaration should consist of clearly defined possible benefits from telemedical procedure, but at the same time pointing that result cannot be guaranteed or assured. It should be enough informative and in the mean

time – defending the patient and his rights. We plan to experiment, giving the opportunity of patients to be comprehensively informed about situations and possible consequences during their telemedical treatment.

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