Ethical and legal issues in the clinical practice of primary health care

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1. ABSTRACT

Since it was conceived, the notion of primary care has been a crucial concept in health services. Most health care is provided at this level and primary care clinicians have an essential role, both in terms of disease prevention and disease management. During the last decades, primary health care has evolved from a traditional paternalistic model, in which patients played the role of passive recipient of care, towards a situation in which patients are partners involved in the decision-making process. This new context opened a considerable number of new ethical and legal aspects, which need to be comprehensively analyzed and discussed in order to preserve the quality of primary health care all around the world. This work reviews the most important ethical and legal issues in primary health care. Legislation issues are explained in the context of the Spanish Health Services.

2. INTRODUCTION

Primary care is an essential and central concept in health services. The first published reference to the concept of primary care is thought to date back to about 1920, when the Dawson Report was released in the United Kingdom (1). That report mentioned "primary health care centres", which were intended to become the hub of regionalized services in that country (2). These centers represented the level at which patients entered the health care system when having a new problem. Some current definitions of primary care are based upon the same notion of first contact (3-4).

These ideas have lain dormant for several decades, until 1978, when the crucial importance of the term "primary care" was recognized by the World Health Organization (WHO). That year, the leading health authorities of around 140 countries met in Alma-Ata at the
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Conference on Primary Health Care. Alma-Ata was the capital of the Soviet Republic of Kazakhstan, located in the Asiatic region of the Soviet Union. There they solemnly approved the Alma-Ata Declaration (5) which spells out the commitments of primary health care and outlines the steps required to promote it. The intention was to create a universal and bold statement. The slogan “Health for All by the Year 2000” was included as a prospective view. In that declaration, the WHO defined Primary Health Care (PHC) as "the essential health care made universally accessible to individuals and families in the community by means acceptable to them and at a cost that the community and country can afford. It forms an integral part both of the country’s health care system, of which it is the nucleus, and of the overall social and economic development of the community. It is the first contact of individuals, family and the community with the national health care system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process. PHC addresses the main health problems of the community, providing promotive, preventive, curative, supportive and rehabilitative services accordingly". This is, by far, the most popular definition of primary care. However, other alternative and complementary definitions have been proposed. An example is the definition made by Vuori (6), who states that primary health care has four distinct facets: it is a set of activities, a level of care, a strategy for organizing health services and a philosophy that should permeate the entire health care system.

The pillars on which primary care stands are the health center and a multidisciplinary health team. The health center is the place where the health team, made up of different health professionals, carry out their work, but also a familiar place to patients, where they can feel safe and they have a close contact with the professionals whose aims are to prevent, promote and take care of their health (7). Primary health care has evolved from a traditional model, focused on the general practitioner, based on a curative approach of the different pathologies, to a new concept of care, developed by family physicians, focused on the patient and their family and social context in which they live. This has turned the former ones into an essential player in the health system's organization since they assume a broader range of responsibilities that can be classified as follows (8):

- Effective and efficient clinical care.
- Integrated care throughout the disease process.
- Focus on the family's health.
- Focus on the community's health.
- Development of prevention and promotion programs regarding the patient, family and community's health.
- Multidisciplinary teamwork.
- Development of educational activities.
- Research functions.
- Use of the scientific method.

Considering these responsibilities, the primary care physician must guarantee a basic level of care, ensuring the comprehensive care and continuity of care in all stages of the patient, family and community's life, and he/she must also manage the resources that the society or state provides within a framework of efficiency and equity, offering access to second-level care (in hospitals) or coordinating social care at home or in supporting organizations.

The practice of traditional medicine has been guided by paternalism, in which the patient took the opinion of only one physician and, guided by carefulness and charity, it has evolved into a culture change in terms of legal ethics in the doctor-patient relationship, demonstrating the autonomy principle according to the principle of personal autonomy, in order to get to a new situation, more appropriate to the times, in which the patient and their rights are thought to be the most important. Patients have seen their role broaden from one of passive recipient of care to involved partner. In this new context, the information provided to the patient is the cornerstone on which a true consent is drawn up. The informed consent would be the last link of users' right to information. In the following sections, the most important ethical and legal issues in the clinical practice of primary health care are summarized and reviewed. Finally, most common ethical and legal barriers to the use of new technologies in primary health care are also outlined.

3. ETHICAL ISSUES

3.1. Principles of health care ethics

Each person has moral and legal rights, thus everyone should be respected and protected. Human rights are based on this principle, of personal dignity. All these rights can be expressed as one: "All human beings must be treated with equal consideration and respect". In the medical field, a particular approach to solving ethical dilemmas has become very popular: the four principles of health care ethics. Developed in the United States, it provides a simple, accessible, and culturally neutral approach to thinking about ethical issues in health care (9). It is defended by authors such as Gillon (10) and Beauchamp and Childress (11). This approach is based on four basic principles: minimizing harm, justice, beneficence and respect for autonomy (12). In spite of that this approach does not provide ordered rules, these commitments can be useful to doctors and other health care workers to make decisions when reflecting on moral issues that arise at work.

The principle of minimizing harm, or non-maleficence (from the latin *primum non nocere* or "first do no harm"). Everyone's life has to be respected and professionals should refrain from any techniques or procedures that may harm the patient.

The principle of justice requires treating all persons without discrimination and with fairness everywhere. It is a broadly fair, equitable and appropriate treatment and implies freedom from discrimination and impartiality.
Beneficence refers to the act of doing good, of acting for the benefit of others. This principle can be seen as the other side of the minimizing-harm principle. It implies the goal of maximizing the potential benefits and reducing the potential harm to the patient. These two principles are closely related, because doing good can be considered as not harming. In fact, the traditional Hippocratic moral obligation of medicine is to provide medical benefit to patients with minimal harm, which is beneficence with non-maleficence.

The autonomy commitment is related to the decision-making capacity of individuals and involves respecting their will and freedom. The physician should avoid paternalism and be respectful of the patient's will, looking for his/her consent honestly, prior adequate information supply. This is the informed consent, which is the highest expression of the autonomy principle because it encapsulates the belief that it is the patient who makes the choice over what procedures to undergo. Even currently, there are people against the patient's autonomy (13), stating that the professionals assume no responsibilities when the patient is allowed to make a decision and the role of the physician is limited to provide relevant information on technical issues difficult to understand. Some believe that patients have taken the autonomy model too far, by demanding treatments that physicians would not recommend. There is considerable support for the view that patients who are ill and fragile may not want to make their own treatment decisions (14-15). However, a considerable body of evidence has also suggested that patients who actively participate in their own care have better clinical results and their demand for health services decreased (16-18).

Different cultures all around the world understand and apply these four common and generic ethical commitments in different ways. As explained in (19), in the American scheme autonomy and beneficence receive the highest priority. However, the Spanish and Continental European tradition relies on absolute principles prior to the empiric autonomy of the individual, which may be summarized in the two basic ethical principles of non-maleficence and justice.

In (20), a stratified random sample of 702 health care professionals was surveyed to determine the frequency of ethical issues in primary care. The study showed that the most frequently occurring issues are pragmatic, not dramatic, and focus on patient self-determination, adequacy of care, professional responsibility and distribution of resources. Palliative care is another area in which ethical issues arise, facing up the provision of medical care. In (21), the basic ethical and legal issues in palliative care are discussed. This discussion includes topics such as the principle of double effect, decision-making capacity, artificial nutrition and hydration, do-not-resuscitate orders, physician-assisted suicide and euthanasia, etc. Evidence-based medicine has the potential to improve patient care, prevent harm, and promote patient autonomy. In (22), the ethical issues raised by evidence-based medicine in the context of primary care are considered.

### 3.2. Ethics in family-oriented medicine

In a broad sense, ethics can be understood as the science of morals, a philosophical concept concerned with human character and conduct. Several authors have provided general definitions of ethics: Fox and DeMarco (23) define ethics as "the evaluation of human conduct". Dowrick (24) makes a separation between the moral and non-moral aspects of human life, and defines it as "the study of the moral aspects of our lives". Thiroux and Krassmann (25) define ethics as related to what is right or wrong in human behavior and conduct. Medical ethics (26) is the human dimension that the physician applies to the professional practice, and which, besides that, as a theoretical and practical science, attempts to apply ethical principles to the resolution of specific cases, by means of the best possible decision that requires a suitable methodology obtained through the study and analysis of cases.

Family Medicine currently has its own area of expertise, research and teaching and this fact requires systematic clinical ethics (27) in order to meet its specific needs. This is the first link for the health care policy and the gateway towards the health system, which leads to the fact that the family physician is daily challenged by making clinical decisions about the patient that must be solved according to some principles aimed at serving the patient and not based on other interests. It focuses on health. This is one of the most important changes in medicine, as we have shifted the center of our attention from the disease care to the prevention and health promotion. This change involves, in many cases, the emergence of new ethical hypotheses, leading to a continuous reconsideration of our activity. The center of attention is the person above anything else, therefore, the primary care professional must be trained and develop a series of personal relation skills. There is an educational function that requires combining the obligation of ensuring the maximum benefit to the people with a deep respect for individual autonomy. This role of health education is a responsibility shared by the primary care professionals, family, school and media.

McDaniel et al. defined family as "any group of people related either biologically, emotionally or legally" (28) and emphasized the necessity of applying a family-oriented approach in primary care, which "involves thinking about a symptom or problem in the context of the whole person and the person's significant others". The family plays a key role in the health-disease process, both in its origin and its treatment, since it is the natural place to be born, live and die. There are situations in which the family's opinion is necessary in order to take the action planning with the patient. An example in this regard is the palliative care, in which the attitude towards the terminally ill patient is giving priority to quality of life above anything else. The development of science, the family's involvement and the professional competence of primary care physicians make it possible to maintain a high quality of life in the home environment, since in most of these cases, patients themselves or their families prefer home care over institutional care.
Table 1. Frequent ethical issues in primary care vs. secondary care

<table>
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<tr>
<th>Related to</th>
<th>Ethical issue</th>
<th>PC</th>
<th>SC</th>
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<tr>
<td>Patient</td>
<td>Confidentiality</td>
<td>x</td>
<td>x</td>
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<td></td>
<td>Diminished autonomy or lack thereof</td>
<td>x</td>
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<td></td>
<td>Giving bad news</td>
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<td>Informed consent</td>
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<td>Lifestyle changes</td>
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<td></td>
<td>Refusal of providing medical prescriptions or certificates</td>
<td>x</td>
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<tr>
<td></td>
<td>Delivery of care to chronic illness or displaced patients</td>
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<td></td>
<td>Palliative home care</td>
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<td></td>
<td>Contraception</td>
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<td>Teamwork</td>
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<td>Distribution of resources</td>
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<td>Relationship with the management team</td>
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<td>Responsibility in long-term training</td>
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<td>Research activity</td>
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<td></td>
<td>Family relationship</td>
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<td></td>
<td>Relationship with other care environments</td>
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<td>Responsibility towards care activities</td>
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Other issues

- Teamwork
- Distribution of resources
- Relationship with the management team
- Responsibility in long-term training
- Research activity
- Family relationship
- Relationship with other care environments
- Responsibility towards care activities

Abbreviations: 'primary care,' ‘secondary care

Society is another aspect which the family physician should evaluate in their work. The influence of society on the individual is very important and this is a priority objective in rural areas. In recent years, there is a need to get involved in health issues within the community, issues which we define as global, such as toxic habits, not individual.

Finally, we should assess the biographical continuity of medical care, as your physician would treat you from childhood to death, period in which you might be suffering from acute and chronic diseases. You should also trust your physician when it comes to confidential matters whose knowledge is relevant in order to receive good health care, hence the confidentiality of the physician-patient relationship. (29-30).

3.3. Ethics in the practice of primary health care

At present, medical care is carried out in several environments, although it could be classified basically into: primary care, conducted in health centers, and secondary care, conducted in specialty centers and hospitals. Some ethical issues are specific to primary care, while others are common. Table 1 shows some ethical issues that are typical in primary care services, in comparison with secondary care ones. They have been classified into two categories: aspects related to patient and other issues.

4. LEGAL ISSUES

In this section, the main legal aspects related to the provision of primary health in the context of the Spanish Health Services are reviewed.

4.1. Requirements for the practice of family medicine

The requirements for the practice of the specialty of family and community medicine are those required by the state for the practice of any other specialty, qualification, affiliation and fiscal registration (in the case of the private practice of medicine).

4.1.1 Qualification

The practice of family medicine requires obtaining two medical certificates to practice the specialty. First, it is necessary to obtain a degree in medicine and surgery - in Spain, the degree course consists of six years of study -, and, secondly, a specialist degree in family and community medicine, obtained in Spain after passing an exam to become a resident member of the medical staff of a hospital (MIR – "Médico Interno Residente" (Spanish), resident physician), and after four years of specialty training in different institutions at both levels, health centers and hospitals. Not having these degrees will result in legal consequences of different gravity, the most serious being those derived from medical practice with no qualification, which is punishable under the criminal code as a crime of intrusion.

4.1.2. Affiliation

At present, the requirement of affiliation for the professional practice of medicine is under doubt and it is related to controversial legal issues. For a long time, it has been accepted the need for compulsory affiliation, within the professional medical associations for the practice of medicine, accepting the possibility of practicing it everywhere in the country, despite the fact of being affiliated only to the medical association where physicians' business or main address is.

This doctrine has been altered by errors which decriminalized the practice without affiliation promoted by governments in different autonomous communities such as Andalusia and Galicia (in this latter, the situation is still the same). Yet, we are still waiting for a final resolution of these issues.

4.2. Professional responsibility

The changes that society has suffered in the field of information, considering globalization and expansion of technologies, as well as people's difficulty to differentiate between true and false information in all media (Internet, newspapers, etc.) lead to the fact that the current trend is to attribute to health professionals the responsibility for damages or injuries resulting from a medical action, existing a presumption that the professional performance has been wrong, and although in many situations it may be due to other suppositions:
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1. Cases related to the malfunctioning of the health care system.
2. Cases of damage not related to medical performance, but occurred as a result of it.
3. Cases of secondary damage or injuries to a diagnostic or therapeutic action completed successfully. (Predictable but inevitable and acceptable risks from a medical viewpoint, or unforeseeable and unavoidable damage as a result of unknown or uncontrollable circumstances).

All these cases make us consider medicine as a risky activity, so the professional should make a benefit-risk assessment of each action individually and the patient should make his/her own decision that is, at present, reflected in the informed consent.

Professional responsibility should only arise when, as a consequence of a negligent or careless action made by a physician or the health service, an injury or damage occurs, which would not have happened if the action had been correct (a recent example is (31)) and not in case of any damage resulting from the health care, as this gives rise inevitably to the practice of a defensive medicine.

4.2.1 Levels of responsibility

Responsibility is the duty of providing competent and effective care whose defective performance is the determining factor of professional responsibility. A physician assumes responsibility by properly fulfilling the duties entrusted, by providing quality services, with dedication and care and by making proper use of the system resources, with loyalty to his/her colleagues and to the organization he/she works for. There are two levels of responsibility: professional responsibility in the course of duties and professional responsibility towards the health system and the administration.

4.2.1.1. Responsibility in the course of duties

The family physician has three main responsibilities: towards patients, colleagues and society.

Towards patients, to whom they should provide the highest quality comprehensive care. It includes the Family physician's duties, as defined by the General Health Law, and which are: the duty of respect for their personality, the duty of disclosure of information, which means providing, in understandable terms, comprehensive, continuous, verbal and written information about their health state, including diagnosis, prognosis and alternatives; duty of consent, which means the free choice between the options available, a prior written consent being necessary to carry out any intervention, except when: non-intervention could endanger public health; the patient is not able to make decisions; when the emergency requires immediate action. As a result of these two duties, the informed consent arises, as defined by the Galician Law 3 / 2001 as the patient's express and written consent, after obtaining the appropriate information to carry out a diagnostic or therapeutic procedure that involves risk. Duty of diagnosis and treatment. Duty of updating knowledge and resources. Duty of professional secrecy. Duty of care and advice. Duty of fulfilling legal certificates and of written recording of the process.

Towards their colleagues, participating actively and cooperating with the primary care team.

Towards society, through a proper use of the resources, by complying with the rules and undertaking commitment to the objectives of the administration.

4.2.1.2. Responsibility towards the health system and management

The family physician, as an employee of a public system, has hierarchical, professional and legal responsibility.

Hierarchical responsibility is related to the obligation of making the decisions and carrying out the activities proposed by the head of the department. And starting from this position, there is a hierarchical structure represented by management, the general subdepartment of primary health care and SERGAS general management of healthcare and the Ministry of Health (Autonomous Community of Galicia, Spain).

Professional responsibility derived from the professional profile and consisting of the tasks contained in the training program of the specialty and the clinical procedures in primary health care.

Legal responsibility, which can be classified as administrative, civil, criminal, ethical and administration's pecuniary responsibility.

1. Administrative responsibility arises from the failure to comply with the rules governing the operation of services and which are included in the medical staff's legal disciplinary system.
2. Civil responsibility is based on the obligation to repair damage, although it was not caused by any fault or negligence. It is of a pecuniary nature.
3. Criminal responsibility arises when a crime or offense is committed deriving from a careless or negligent action, entailing a penalty of deprivation of freedom, civil and administrative responsibility. Both the civil or criminal responsibility obligation concerning the professional is rather related to means rather than results, according to the state of science and lex artis (law of the skill). The lex artis could be defined as a set of rules and principles, which, as a result of being socially accepted, regulate the basis of the professional duty and that could be summarized as follows: Duty of adjusting professional performance to the techniques, legal standards and ethical principles; Duty of education and continuous training in order to adapt knowledge and skills to a ceaseless scientific progress and professional experience; Duty of avoiding risky procedures, that is, not performing any procedure which one is not properly prepared or has not been qualified for.
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4. Ethical responsibility. It refers to the principles and duties of professional ethics that may lead to failure to comply with the Code of Ethics of the Medical Association Organization.

5. Administration's pecuniary responsibility. When damage occurs due to the operation of public services.

4.3. Legal documents in primary health care

One of the common tasks of the primary care physician is filling out documents. In this section, the main characteristics and examples of medical and medico-legal documents in the context of the current Spanish legislation are described. Generally, primary care documents must fulfill the following characteristics:

- They must be written.
- They must be signed by the patient and the physician.
- They must be in accordance with the requirements of legal proceedings.
- They must have a lawful purpose, a content and be original.
- They must be legitimate and truthful.

A distinction must be made between medical documents and medico-legal documents.

4.3.1. Medical documents

They are of great interest due to their economic, administrative and legal implications, which has led to a regulatory development of document activity and, in particular, of medical history and all documents related to the disclosure of information and informed consent.

Various laws have been developed in the Spanish autonomous regions, Catalonia (2000), Galicia (2001) and Andalusia (2009), by means of regional laws on the regulation of information, consent, preservation and access rights to the medical history. The living will document has also been regulated.

4.3.1.1. Medical history

The medical history will be made up of the documents of the medical care, prevention and health promotion initiatives, covers the individual's state of health and it consists of a set of legal and welfare documents that enables the citizens' right to the availability of the information contained in their medical histories and their appropriate use in health care. It is of great medico-legal interest because in certain circumstances it can be used as evidence for legal proceedings.

4.3.1.2. Informed consent

The informed consent will be the last link of this process. It is fundamental to the patient-physician relationship that each partner understands and accepts the degree of autonomy the patient desires in the decision-making process. It is also important to consider that restrictive interpretations of some of the recent guidance on patient consent would damage surveillance mechanisms to such extent that they would cease to protect the public, thus resulting in preventable ill health and deaths.

The informed consent, properly understood, must be considered an essential ingredient of good patient care, and a physician who lacks the skills to inform patients appropriately and to obtain proper consent should be viewed as lacking essential medical skills necessary for practice. However, the acceptability to patients of access to medical records without their consent is frequently assumed. In the UK, an exploratory study highlighted a number of areas of public concern when medical records are accessed for research without the patient’s consent.

It is also important to consider that restrictive interpretations of some of the recent guidance on patient consent would damage surveillance mechanisms to such extent that they would cease to protect the public, thus resulting in preventable ill health and deaths.

There is a consensus on considering that an individual is autonomous when making decisions:

1. Ability to understand the information provided.
2. Ability to understand the consequences of each decision.
3. Ability to develop reasoning based on the information that he/she is transmitted and his/her scale of values.
4. Ability to announce the decision made.

An external circumstance must be considered besides these four conditions: the absence of coercion.

Only physicians can carry out the essential clinical and therapeutic interventions for the patients' health, without their consent, in the following cases:
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1. When there is a risk to the public health because of health reasons established by law and so expressly stating in accordance with the provincial delegate of the Ministry of Health or the General Director of Public Health if more than one province were affected. And they will be reported to the judicial authority within up to twenty-four hours provided the compulsory admission of people is available.

2. When there is an immediate serious risk to the patient's physical and psychic integrity and it is not possible to obtain the authorization, consulting, when circumstances allow it, their relatives or other close persons.

4.3.2. Medico-legal documents

These are documents created in order to serve as a means to prove something (a certificate) or as evidence in a potential legal proceeding (injury medical report, expert report). These documents are mandatory and must be done with legitimacy and veracity.

4.3.2.1. Certificate

It is a document that gives evidence of a fact or facts that the physician has verified by clinical exams and/or complementary tests conducted on the patient or by having witnessed the disease. This document has two medico-legal characteristics:

1. Exempting the physician from their professional secrecy obligation since it is issued at the request of the interested party.
2. Not being addressed to anyone in particular.

Among these certificates, there are also:

1. A death certificate (which must be issued by the physician who has treated the patient in his/her last illness, and who in the case of primary care is often the physician from the health center) and
2. The medical health certificates.

4.3.2.2. Medical certificates and reports

These documents are used to notify the authorities about different facts related to medical practice; the most used ones by the primary care physicians are the temporary disability certificates (for sick leave), those reporting infectious diseases and the injury reports.

The temporary disability certificates are essential to implement the protective action of social security when a worker goes through a pathological process that prevents them from carrying out their normal working activity. There are three types of documents for temporary disability: Medical certificates for (a) sick leave (b) extension of sick leave and (c) end of sick leave.

An injury medical report is a document that must be issued whenever an individual who has an injury or has been poisoned or has undergone an abortion is treated, in order to report to the judicial authority about it, so that it can carry out relevant research and take the appropriate measures.

The certificates reporting infecto-contagious diseases must be issued whenever an individual who has a notifiable disease, which involves a set of health problems, infectious diseases, requiring epidemiological surveillance and specific preventive actions, is treated, in order to notify the health authority and public health about it, so that relevant research could be carried out and the appropriate measures could be taken. Depending on the classification of the notifiable diseases, the certificates may be of different types: weekly number, case detail and urgent reports.

5. ETHICAL AND LEGAL ASPECTS RELATED TO THE USE OF TECHNOLOGY IN PHC

Fragmented and inaccessible clinical information adversely affects both cost and quality of health care as well as endangers patient’s safety. Advances in information and communication technologies are viewed as an essential tool in solving these problems and promoting better health care (39-42). They provide multiple benefits such as: enhanced patient autonomy, improved clinical treatment, improvements in health research and public health surveillance and modern security techniques (43). As these advances are being applied with increasing regularity in the primary care domain, all the involved parts (i.e. ethicists, lawyers, computer scientists, general practitioners and patients) must deal with a variety of ethical and legal problems (44).

Since the first discussions related to the widespread introduction of computer programs in clinical medicine (45), ethical and legal implications of handling health care information have been strongly modified during the last 20 years, and there are a lot of challenges yet to come (46). The field of health technology assessment (HTA) is proposed to face some of these challenges, by arguing that a value analysis is crucial to overcome the ethical issues of health care technology in a fruitful way (47).

There are important social, ethical and legal barriers that impede the wide-scale adoption of new technologies, such as Electronic Medical Records (EMR) systems (48-49), in health care. The results of a study (50) regarding the use of information technology in primary care indicate that physicians in general perceive benefits of the information technology, but also state that legal issues constitute a major barrier to its implementation in their practices. Overcoming these barriers will require a diversity of efforts, such as subsidies and incentives, certification of vendor applications, removal of legal barriers, and greater security of medical data. Hodge et al. identified 3 main interconnected areas in which legal challenges arise: privacy of identifiable health information, reliability and quality of health data, and tort-based liability, and provided some recommendations for legal reform with respect to these areas (43).

The implications of specific technologies have also being studied. As an example, benefits and disadvantages of using e-mail technology in medical
practice have been analyzed in (51). While busy professionals admit that e-mail is a timesaving tool, there are certain risks in using e-mail for patient dialogue that need to be considered. Also, a recent work (52) regarding the use of new technologies to inform patients about the results of blood tests has revealed that patients would prefer e-mail, rather than SMS or web pages.

Another important aspect that requires attention is Quality Improvement (QI). Health professionals, managers, delivery organizations, patients, and government, all have an ethical responsibility to cooperate with one another to improve the quality of care. QI strategies and activities have also been positively influenced by recent technological advances (53). However, some authors emphasize that QI activities must be conducted ethically (54-55). Attempts to improve quality may inadvertently cause harm, waste scarce resources, or affect some patients unfairly. For example, efforts to encourage cancer screening may prompt useless, risky, and expensive tests in people who are too near death to benefit from them. Also, the issue of sharing patients' data for the purpose of quality improvement was recognized as an ethical problem (56).

### 5.1. Effects of technology in the patient-physician relationship

The patient-physician relationship is fundamental to the successful delivery of primary health care (57). Traditional models for the patient-physician relationship have been proposed and debated. In (58), four models are presented: informative, interpretive, deliberative and paternalistic. Other work (59) explored the different communication patterns in primary care through audiotape analysis and questionnaires, and revealed 5 distinct communication patterns: narrowly biomedical, expanded biomedical, biopsychosocial, psychosocial and consumerist. Patient satisfaction was highest in the psychosocial pattern, which reveals the importance of the quality of interpersonal care to patients. Studies suggest that increasing patient involvement and participation in the care process improves patient satisfaction (60-62).

Nevertheless, recent technological advances and their inclusion in routine primary health care are affecting traditional patient-physician relationship in an important manner, and new ethical and legal aspects need to be considered. Despite having a number of benefits, the use of new technologies can lead to deteriorated communications and a poorer relationship between doctor and patient (63). Physicians must take precautions to keep patient information confidential, to preserve patient information trust and integrity of the patient-physician relationship. From a medical ethics viewpoint, the American Medical Association (AMA) states that "new communication technologies must never replace the crucial interpersonal contacts that are the very basis of the patient-physician relationship" (64).

Patient-physician relationship is affected by health information available on the Internet, including the Web 2.0 (65). Accurate information is a benefit, while inaccurate information can be harmful. A study (66) revealed that actions are required to overcome the digital divide: assisting the public in developing searching and assessment skills and ensuring that physicians have adequate communication abilities. Other study by Murray and colleagues (67) concluded that physicians seem to accept clinically inappropriate requests generated by information on the Internet. The fear of damaging the patient-physician relationship is viewed as a possible cause. However, Stevenson and colleagues (68) concluded that doctors need not feel challenged when patients bring information from the Internet. They should see it as an attempt on the part of the patient to work with the doctor and give a positive response. A study on patients affected by prostate cancer (69) suggested that online information provides patients a method of taking some control over their disease and limiting inhibitions experienced in face-to-face meetings.

Regarding e-mail, its effects on the patient-physician relationship have been studied in (70). Ling Leong and colleagues concluded that e-mail has the potential to improve the doctor-patient relationship as a result of better communication (71). Nevertheless, a recent systematic review of 24 published studies on e-mail communication between patients and health providers (72) concluded that additional efforts are needed to educate patients and physicians in the use of e-mail for communication.

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