Ethical Analysis of Information Systems (IS) In Health: A Model for Understanding Expectations and Actual Achievements to Stakeholders Involved In the IS

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Abstract

Objective: Study the initial expectations and the final realization of Information system (IS) with health professionals.

Methods: Our study is done from two questionnaires includes 40 items (Q1 and Q2) based on modeling ethics. This model is constructed using four universal ethical principles: autonomy-beneficence—non-maleficence-justice, and the TCO-TCM methodology. It meets the environmental parameters of the real: medical and technological-policy and structural-organizational and regulatory-cultural and relationships. We interviewed 26 players consisting of 14 designers IS and 4 respectively responsible for consulting firms, publishers of IS and hosting of medical data. A score ethics unit/100 were used to assess the ethical expectations (Q1) of the actors and the achievement ethic (Q2) for the SI.

Results: The score ethical expectations unit (Q1: 78.7) of IS is higher than that of the realization (Q2: 63.7) of IS (p<0.001). The subscores ethical expectations belong in order of importance to ethical principles: beneficence (84.9)-autonomy (78.9)-non-maleficence (77.2)-justice (73.9). Subscores ethical achieving a mean SI (in order of importance) the following ethical principles: autonomy (67.3)-beneficence (63.0)-non-maleficence (62.1)-justice (58.6). The score ethical expectations unit (Q1) is higher than that of the realization (Q2) to all categories of protagonists (except the hosts of health data). Gives the same results if we study all the subscores principle by principle. Offer Ethics (Q2) of the editors of SI is still below expectations ethical (Q1) of actors involved in contracting owner (MOA) of an IS healthy. Offer Ethics (Q2) of the hosts of health data is always higher ethical expectations of the actors involved in the entire MOA of an IS.

Conclusions: The application of our modeling ethics for study of the expectations and achieving a health IS results in the coherent set according to the nature of the principles and stakeholders. This reflects a degree of accuracy of the assessment tool for health IS healthy. There is a double confrontation, on the one hand, between autonomy and beneficence, and also between non-maleficence and justice, according to the expectations and the realization of IS with the protagonists. By highlighting this model based on ethical principles and environmental parameters of reality, our work contribute to make the initial foundation of the architecture ethics of a health IS.

Keywords: Information system; Modeling; Ethic; Principles

Introduction

The organization of health systems is going through several years of difficulties multifactorial (disruption of mentality, clashes of views on policies to control health care costs). A feeling of “chaos” occurs [1], where before a semblance of order prevailed, values, principles and rules established. Now, our health systems and in general our societies returned to an era of questioning. In this article we focus on questions concerning the potential part of these Information Systems (IS) and ethical issues they should consider [2]. For example, the handling and use of medical information that IS we can find in constant balance between confidentiality (heart of medicine discipline) and transparency (heart of the public sphere) [3]. Given these facts, how should we think about the implementation of coherent information system and what ethical dimensions have to comply?

Does the computerization of medical data implies a risk, or does it reveal a decline of some social and moral foundations of medicine such as privacy and security of medical information? The right to access and legitimacy of this information are they challenged [4,5]. In general, the concept of confidentiality [6,7] is it still “fashionable” and its meaning in the modern democratic society? So many questions characterize a certain anxiety and a loss of confidence among health actors, in the very values of our health systems, resulting in an overall feeling profoundly destabilizing.

In this context, the major challenge of our research is to propose a model for analyzing ethical aspects of an IS. This analysis model allows to know if the realization of an IS is in line with initial expectations of stakeholders. This work was carried out in health facilities in the Bouches-du-Rhone (France). The objective is to compare an ethical score to original objectives and the final realization of the technological tool with people involved in it.

This enhancement of the ethical dimension of an IS requires us to work simultaneously in both directions, that of the person and the system itself, in order to ensure the required degree of consistency. This is why turning an IS into an ethical system depend on the nature of the ethical standards that surround said system [8-11]. This ethical

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framework will help us to provide guidelines dictated by the short-sighted pragmatism, the quest for power, economic interests, etc.

Methods
Presentation of the approach

To resolve complex ethical issues or ethical dilemmas of IS, it is necessary to go through a step of analysis. We are using a method of examining ethical issues with a number of benchmarks from the standards and legal and ethical rules, theories and ethical principles, and approaches in bioethics. These are both designed as a tool in solving the problems of ethics and as beacons marking the ethical dimension in practice.

The reflection on the nature of an IS needs to take into account, not only the tool of a technical point of view but also from an ethical standpoint by the purpose and impacts it generates.

In this sense, the positioning of technological aspect occupies a place in the middle, between the tool and the natural environment. From a literature search on the subject [1,12-15], we were able to distribute the “environmental parameters of the real” in four specific areas of order: Structural and Technical (ST), Policy and Procedural (PP), Organizational and Regulatory (OR), Relational and Cultural (RC). These “keys to understanding” multisectoral of reality are interrelated and therefore can give a value application and concrete ethical framework.

From these, we conducted a field survey on different IS in health by making initially, targeted interviews with officials of the IS and its users. In a second step, we completed the field survey through a questionnaire based on an ethical model consists of universal ethical principles: autonomy, beneficence, non-maleficence and justice as well as «environmental parameters of the real» we have seen before.

In order to establish the most complete analysis of the ethics of IS in health, we collected the views and concerns of all stakeholders in the life cycle of an IS (Figure 1).

Thus, analysis questionnaires1 have analyzed the IS in 14 health facilities2 involved in the treatment of cancers in the Bouches-du-Rhône, 4 consulting firms, 4 editors of IS and 4 hosts of health data.

So we interviewed 26 participants consisting of 14 designers IS for health facilities and 12 business leaders involved in IS. The selection of

1That is to say Q1 on ethical expectations of the players before the development of the IS and Q2 on the achievement ethic SI after its introduction.
29 hospital services for medical imaging - 4 departments of multidisciplinary meeting (RCP) - a management structure to prevent against cancer in Provence-Alpes-Côte d’Azur (PACA)

Figure 1: Stakeholders in the life cycle of an IS.
participants has been established on the following inclusion criteria: the respondent must necessarily be responsible for the implementation of its IS. Indeed, this parameter is fundamental because it is essential that the individual may have a clear picture of the actual implementation of its IS in its establishment.

Since most of these health facilities involved in the study have a person who combines both the position of the building owner and the master (MOE), we cannot analyze specifically the role of MOE. The analysis of the building owner and "internal" users, hosts health data personal and consultancies master owner (MOA) will be made through this statistical study (through questionnaires).

The questionnaires allowed us to establish scores of ethical unit on 100 of the expectations of these actors and the realization of their IS healthy. Respecting these conditions, we have to compare and cross the questionnaire (Q1) on the analysis of the major objectives of an IS initiated by the designer and manufacturers with the questionnaire (Q2) to study the implementation and characteristics of the IS tool in health after it is established.

**Representation of the ethical model**

The application of this model and concepts leads to a rational analysis and quantitative principles to implement [16]. So we study design, implementation and use of IS in health by investigating specific areas and concrete. This multi-sectoral environment constitutes « the real justifications », real keys to understanding the reality, represented by a variety of areas such as structure and technology, organization and regulation, strategy and methodology, and the relationship cultural. Thus, this model will be seen in three aspects interact:

- The first view, called ontological (or structural aspect), considers the IS in its structure. The vision of « being » of the device
- The second view considers the functional aspect of IS in its function. It is the vision of « doing » of the device
- The third point of view, said gene (or dynamic aspect), considers the IS in its temporal evolution. It is the vision of « becoming » of the device.

Finally, clarification of personal values, professional, institutional, is a prerequisite for any reflexive ethics of health. This model is therefore the ethical foundation on which our questionnaires were constructed for analysis essential to our study site. It should not be used as a rigid framework, but rather as a flexible structure to incorporate into the design, implementation and use of the SI of the health facility.

**Foundation on which our study questionnaires and our score ethics unit**

We used the same media questionnaires that we have done previously for an article for the journal European Journal of Telemedicine, entitled « Evaluation éthique des SI auprès des acteurs de santé ». These questionnaires are considered as a tool for assessing the objectives of an IS in health was developed with consistent results indicating a certain reliability of this model ethics. Note that the questionnaires Q1 and Q2 are identical and consist of 40 items that represent the main objectives of an IS (Table 1). These items are grouped evenly balanced between the ethical principles (B-J-A-NM) and environmental parameters of the real (PP-RC-OR-ST). 10 actions correspond to the four ethical principles.

We integrate these 40 items to enrich our ethical model. The objective is to compute a « score ethics unit » of the four ethical principles from the treatment modalities of the questionnaire shown in Table 2. This score represents the sum total of 40 items corresponding to the four universal ethical principles: autonomy, beneficence, non-maleficence and justice. Sub-scores are also calculated for each of these principles.

**Statistics**

Internal consistency (homogeneity) of measuring instruments was evaluated by calculating Cronbach’s coefficient α. Paired Wilcoxon tests were used to compare responses between the two questionnaires and for pairwise comparisons of various sub-scores. The Kruskal-Wallis tests were used to compare the scores ethics unit and subscores according to professionals’ group. A p-value less than 0.05 were considered statistically significant for all bilateral tests used. All analysis was performed using SPSS 17.0 (SPSS Inc. Chicago, IL).

**Results**

**Score ethics unit according to the 4 ethical principles**

From the questionnaire 1 (Q1) and questionnaire 2 (Q2), we have respectively set up a score ethics unit expectations and the achievement ethic of an IS on all the 26 actors who participated in the study with a high internal consistency (α > 0.9). The score of ethical expectations of an IS (Q1) was significantly (p < 0.001) higher than the score of achievement of IS (Q2) (78.7 vs. 63.4) (Table 3). In addition, we obtain the same trend for each sub-scores of ethical principles in Q1 compared to Q2. From these sub-scores, we were able to make following observations:

- Expectation (Q1) for an IS on ethical principles (in order of importance): Beneficence (84.9) > Autonomy (78.9) > Non-maleficence (77.2) > Justice (73.9).
- The realization (Q2) of IS involves ethical principles (in order of magnitude): Autonomy (67.3) > Beneficence (63.0) > Non-maleficence (62.1) > Justice (58.6).

**Score ethics unit according to the professionals involved in IS in health**

The score ethics unit expectations of an IS was higher than the score of achievement of an IS for all categories of actors (except for hosting4) (Table 4). However statistical significance was reached only for the nine actors involved in medical imaging (p = 0.008). When we established the difference between the respective score ethics unit expectations and achievement, we found the following ranking: Imaging (+ 22.7) > RCP (+ 19.2) > Publisher (+ 18.3) > Consulting (+ 12.5) > Management structure (+ 7.5) > Host (+ 3.5) (Table 4).

We get the same results if we analyze all of the ethical sub-scores principles one by one. There is no significant difference between expectations and the realization principles one by one according to the actors except for the nine players in medical imaging. From Table 5, we find that:

- 5/6 (83%) of the players think that the principle of beneficence is the most important5 the objectives of an IS;
- 4/6 (67%) of participants consider that the ethical realization

4Cf. Environmental parameters of reality.
5Considering the results, it appears that the hosts are a special case of the other players. This may be due to the fact that there IS dedicated to the storage of medical data to differ significantly from IS studied here whose primary mission is to help support patient care.
6With an ethical sub-score in Q1 higher than the other three principles.
1. To Assist in the medical decision-making established by the health professional (B-PP)
2. To promote the quality, organization, management and planning supported the patient (B-OR)
3. Working for well-being of the patient (B-RC)
4. To Share common informations, transparent and accessible (B-PP)
5. To Ensure the quality and choice of information transmitted (B-ST)
6. To Improve the continuity of care (B-PP)
7. To Support the monitoring of all health activities (B-PP)
8. To Evaluate the performance and identify areas where action is required by listing the points of failure (J-PP)
9. To Manage effectively the health facility containing costs (J-RC)
10. To Assist the Ministry of Health to meet expectations and the management of cancer in users of health (B-RC)
11. To Establish legitimacy of law and information processing (B-OR)
12. To Establish a duty of safety, integrity, traceability and protection of medical data (B-ST)
13. To Improve and enhance interactivity with actors outside the health facility (J-RC)
14. To Increase the availability of health actors (J-OR)
15. To Facilitate access to medical information to all users: Reducing social inequalities (J-ST)
16. To Follow the same rules of access and dissemination of information regardless of the profile or status of the patient (J-OR)
17. To Divide equally disadvantages and benefits of such a tool in the workload of health professionals (J-PP)
18. To Share the same information and the same medical decision support to all health professionals involved in the circuit of the patient within the structure (J-PP)
19. To Develop and to share accurate information and appropriate to the entire population (J-PP)
20. To Provide epidemiological analysis or statistics (SAE) (J-ST)
21. To Empower the conduct of users care to the community (NM-RC)
22. To Develop a collective performance-oriented organization (NM-OR)
23. To Minimize or to eliminate the harm done to patients due to mis-information (NM-RC)
24. To Replace the patient at the center of the decision by providing medical information more complete and rapid (A-ST)
25. Ensuring Consent and patient compliance (A-RC)
26. To Respect the privacy, the right to confidentiality and privacy (A-RC)
27. To Respect the right to prior information, correction and opposition described (A-OR)
28. To ensure the reliability of medical data collection and ongoing (NM-ST)
29. To Establish a single use and / or collective medical information (A-ST)
30. To reduce the information asymmetry between doctor and patient: Best balance of the doctor-patient relationship (A-RC)
31. To Follow the statutory regulation of medical data (NM-OR)
32. To Respect the rules of storage, hosting and distribution established by the CNIL (NM-OR)
33. To Maximize the use of medical information: Quality ethics of medical decision (NM-OR)
34. To align the use of medical information with the organization of the health facility (A-OR)
35. To Establish a management policy and control the use of medical information (A-PP)
36. Strengthening the transversal services within the health facility (A-OR)
37. To Adapt technology knowledge and skills of health professional (A-ST)
38. To Be sure that the means used must not exceed what is necessary to achieve the desired objectives (NM-PP)
39. To Reduce unnecessary risks or miscalculated (NM-PP)
40. To Ensure the technical relevance and human merits of the IS (NM-ST)

Table 1: 40 major ethical objectives of an IS in health.

| Terms of questionnaire analysis. | Score ethics unit | Realization (Q2) |
|---------------------------------|-------------------|------------------|
| Mean                            | Standard deviation| Mean              | Standard deviation| p     |
| Expectations (Q1)               |                   | Realization (Q2)  |                   |       |
| Mean                            | Standard deviation| Mean              | Standard deviation|       |
| Score ethics unit               |                   |                   |                   |       |
| Beneficence                     | 84.9              | 11.9              | 63.0              | 15.4  | <0.001 |
| Autonomy                        | 78.9              | 12.4              | 67.3              | 15.8  | 0.001  |
| Non-maleficence                 | 77.2              | 14.5              | 62.1              | 18.2  | <0.001 |
| Justice                         | 73.9              | 15.9              | 58.6              | 18.9  | 0.001  |

Table 2: Terms of questionnaire analysis.

Table 3: Comparison of expectations and the realization of the score ethics unit and sub-scores (n = 26).

| Expectations (Q1) | Realization (Q2) |
|-------------------|------------------|
| Mean              | Standard deviation| Mean              | Standard deviation| n  | p     |
| Imaging           | 85.5             | 10.3              | 62.5              | 8.8     | 9  | 0.008 |
| RCP               | 76.9             | 12.4              | 57.7              | 9.9     | 4  | 0.068 |
| Management structure | 57.5        | 14.5              | 50.0              | 18.2    | 1  | NC* |
| Host              | 73.5             | 13.5              | 82.1              | 10.6    | 4  | 0.197 |
| Publisher         | 81.0             | 5.7               | 62.7              | 21.0    | 4  | 0.109 |
| Consulting        | 68.3             | 10.3              | 55.8              | 6.5     | 4  | 0.068 |

*The statistical test cannot be calculated with a single management structure NC=Not calculable

Table 4: Comparison of score ethical unit expectations and the realization of health facilities.
of their IS best meets the requirements of the principle of autonomy;
- 5/6 (83%) of the players think that the principle of justice is the least important with respect to the objectives of an IS;
- 3/6 (50%) of stakeholders consider that the ethical realization of their IS meets the least the requirements of the principle of non-maleficence.

The offer publishers of IS it is in line with the demand of players (Designer of IS (MOA) and Consulting (AMOA))?

To answer this question, we compared the realization of the publishers of SI (Q2) with the initial objectives of the actors involved in the MOA and AMOA (Q1) (Table 4). These results indicate that the offer made by publishers (62.7) tended to be below the expectations of these players (68.3 for consulting firms and 81.0 for designers of IS).

The offer hosts of health data personal is it in line with the demand of players (Designer of IS (MOA) and Consulting (AMOA))?

To answer this question, we have to compare the realization of hosts of health data personal (Q2) with the initial expectations of those involved in the MOA and AMOA (Q1) (Table 4). These results indicate that the offer made by the hosts (82.1) is always above the expectations of the actors (68.3 for consulting firms and 81.0 for designers of IS).

Discussion

Overall, our results show that the expectations of actors for an IS and the effective realization of the latter concern mainly the ethical principles that directly the person in the moment and have a more individual and collective. Therefore, the principle of beneficence and autonomy predominate. Indeed, they have a dimension of the instant and the moment through one dialogue of the person. They belong to the microscopic vision of the clinic. For its part, the principle of justice is perceived by stakeholders as being the least important to compose the objectives and the development of an IS. Because it is only indirectly involved in the doctor-patient relationship, it seems that this principle does not fall within the primary concerns of professionals. It belongs to the dimension of anticipation and projection to events that could happen for a whole person. It corresponds to a macroscopic view of the clinic.

In addition, the principle of autonomy dominates so in the realization of an IS, offsetting the principle of beneficence to the expectations. This symbolizes the passage of a “medical paternalism” reflecting the passivity of the patient in an “enlightened paternalism” in which the patient becomes an actor of his health. Now beneficence has for actor the doctor but also the patient. The principle of autonomy opposes a paternalistic practice where the caregiver that the patient could better what would be the good of it. This medical paternalism corresponds well to conflict between beneficence and autonomy.

Table 5: Comparison of ethical sub-scores expectations and the embodiment of health facilities.

![Table 5](image_url)
Furthermore, by analyzing the ethical sub-scores the highest by principle to the expectations and the achievement of IS, there is a confrontation between autonomy and beneficence as actors, because the two principles are involved directly in the doctor-patient relationship. They have the same dimension of the present moment through the doctor-patient relationship. When we study the ethical sub-scores the lowest by principle, there is a cons-balancing between justice and non-maleficence as actors, the fact that these two principles are involved indirectly in the doctor-patient relationship. They have the same dimension, that of anticipation to facts that could happen for the community.

In addition, the management structure to prevent against cancer in PACA is the only institution for which the principle of beneficence has ethical sub-scores the lowest for the expectations as for the realization of an IS. This may reflect the fact that the institution is a management structure for cancer prevention. The nature of this property is in line with the principles of justice and non-maleficence, hence their ethical subethical higher than the beneficence.

Finally, the offer editors of IS is not generally in line with the request of those involved in the MOA as a whole. However, the ethical realization of publishers is close ethical objectives consulting firms for IS. For its part, the offer of hosts of health data personal is also not in line with the request of stakeholders in the (A) MOA. However, the ethical realization of hosts around the ethical objectives of the designers of IS.

Conclusions

An information system is especially useful relations through which it acts as a support and sometimes it creates. Information is the symbol, the key and the condition of human interaction because it facilitates trade. However, information can be a nuisance if it represents a vector of the desire to dominate, and becomes a barrier against transparency. Meet the ethical demand generated by the hazards of a new world that condition the market and Information and Communication Technologies (ICT), particularly in medicine, one cannot help wondering about the counterweight, corrections and regulations put in place. Rules of the game seem a priori necessary. They are not just an ethical of relational, but also a technical necessity, essential for the patient to form an opinion on the options.

Far from the intention of creating a record for pioneering for the health actors, our research offers the reader some ideas being considered for the design, think and use the IS as an ethical issue while taking into account the problems and fluctuations of political, strategic, technical, organizational, regulatory, relational and cultural that such a device create. These tracks are used to organize ethical reflection of an IS from its creation to its use through an ethical model. It requires the construction of an evaluation system resulting in the creation of a score ethics unit and ethical sub-scores by ethical principle.

Thus, the application of our analytical model has been able to show that an ethical realization of an IS is never consistent with the high expectations for the same actor (except for the hosts). We are entitled to ask whether such a shift is not from the means in place to achieve those expectations. In addition, unlike the hosts, the ethical offer of publishers of IS is still below the expectations of those involved in the MOA of an IS in health. Moreover, the principle of autonomy prevails in the implementation of an IS, offsetting the principle of beneficence expectations. It has been well demonstrated through these ethical scores that patriarchal society of the past has given way to a more democratic society where the weight of the principle of autonomy prevails over that of beneficence. The aim is to promote beneficence and therefore differs from paternalism, and therefore that is based on autonomy. The idea is that this is not the social body, the medical profession, which determines the beneficence but this is now the subject.

According to Pierre Le Coz, such a principle cannot be separated from that of autonomy, «since being beneficial to the patient returns to meet his personal representation of what is best for him, the principle of beneficence would lose sense if apprehended separately from the principle of autonomy» [17]. To resume, it should not be allowed to do good of a person against his will.

As we have seen throughout our work, a medical decision has acquired, in addition to its individual dimension (principle of autonomy, beneficence and non-maleficence), a collective dimension (the principle of justice) which must complex ethical requirements. These requirements implied by the “skills” thus become more acute under the pressure of technical “know-how” [18]. It seems urgent to reintroduce the ethical dimension in training medical and nursing original designers and users of IS. This will increase the price of painful questioning the usefulness of techniques already developed and socially adopted as “standards” among health actors.

Finally, our study will develop in the near future a “code of ethics” on the design, implementation and use of an IS in health.

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