ETHICAL EVALUATION MODEL FOR TECHNOLOGIES.
THE ROLE OF MEDICAL TECHNOLOGY IN THE DEVELOPMENT
OF AUTONOMY IN DIABETES PATIENT

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ETHICAL TECHNOLOGY ASSESSMENT MODEL. ROLE OF HEALTH TECHNOLOGY IN THE DEVELOPMENT OF AUTONOMY IN DIABETIC PATIENT (Abstract): Romanian Government Decision (GD) No. 8/2012 amending and supplementing GD No. 144/2010 regarding the function and organization structures of the Ministry of Health defines health technology assessment (HTA) as "a systematic and multidisciplinary analysis of the existing and new medical technologies, through which medical, economic, social, ethical and organizational information are synthesized so that medical technologies to be used in a transparent and unbiased manner". We propose an ethical assessment model of technologies used in the care of diabetic patients. The nature of this research was exploratory, giving the novelty of this approach to the clinical and social context of Romania. Material and Methods: The assessment of health technologies used in the care of diabetic patients was based on the following research question: What is the role of health technology in developing autonomy and responsibility in patients suffering from chronic diseases? Individual interviews and focus groups were held from June, 2011 to November, 2012 in Iasi. The criterion for selecting the participants was belonging to the target groups: family doctors or diabetes specialist, patients with type 1 (T1D) and type 2 diabetes (T2D), caregivers and other professionals involved in diabetes patient care. Results and conclusions: The diabetic patient benefits from a specific treatment and has the privilege of self-administering it, his life expectancy and quality of life depending upon the compliance and responsibility he demonstrates. Keywords: ETHIC EVALUATION, TECHNOLOGIES, AUTONOMY, DIABETES PATIENTS

Health Technologies (HT) are variously defined. One approach is based on interventions and defines HT as a wide range of products used to diagnose, monitor or treat a disease or medical condition, aimed at improving the quality of healthcare provided to patients with an early diagnosis, less invasive treatment options, and shorter hospital stay and recovery time (1,2). Another definition is focused on structure, HT being understood as "medical services, drugs, medical or surgical instruments and techniques used in health care as well as the organization and support care system provided" (2,3). Health technology assessment (HTA) is necessary for both economic and ethical reasons, HTA meaning "a comprehensive strategic research form (Policy Research) which explores the direct and indirect consequences, intended and unintended, short-and long-term technology applica-
Ethical evaluation model for technologies.

ations, or a systematic evaluation of properties, effects and/or other impacts of technologies in health care" (2,3).

**National legal framework regarding health technology assessment**

Romanian Government Decision (GD) no. 8/2012 amending and supplementing GD no. 144/2010 regarding the organization and function of the Ministry of Health defines health technology assessment as "the systematic and multidisciplinary analysis of the existing and new medical technologies, through which the medical, economic, social, and ethical information on the use of health technologies are synthesized in a transparent and unbiased and manner " (GD 8/2012). The lawmaker believes that "the purpose of health technology assessment is to provide information support for the formulation of an effective, safe, patient-centred health policy and making decisions that ensure obtaining the greatest possible added value" (GD 8/2012). We draw attention on the approach specific to utilitarian ethics used by the lawmaker in HTA. This assessment is applicable to drugs, medical devices, equipment and advanced medical techniques, health policies, medical services and procedures, organization and management of health systems, including those covered by national health programs (GD 8/2012).

In Romania, the institutional HTA agency is the Ministry of Health which is the competent national authority in this field (GD 8/2012).

**The principlism approach of ethical assessment of health technologies**

Principlism was first formalized in a document called the Belmont report and the four bioethical principles proposed by Beauchamp and Childress. These four principles in the interpretation of Ion Mureșan (4) are:

1) autonomy: respecting the ability of autonomous individuals to make decisions, giving them the freedom to make choices regarding their life according to their conscience;

2) beneficence: requires weighing the benefits against costs and risks - including the duty of aiding others to promote their interests;

3) nonmaleficence: human subjects should not be harmed, the actions causing more harm than benefits being avoided;

4) justice: consists in a group of norms for fairly distributing benefits, risks and costs - fairly distributed medical goods and services (4,5).

Ion Mureșan shows that the four principles of Beauchamp and Childress are therefore the core of what the authors call "common morality", meaning fundamental moral norms shared by all morally serious persons in all places. Therefore this procedure was called "the four principle bioethical approach" or "principlism" (4).

The assessment proposed in the present research exclusively considers the autonomy principle and the role of health technologies in the development of autonomy and responsibility of chronic patient for his health. For Beauchamp and Childress (5) autonomy is self-empowerment outside the control and intervention of others which generates a meaningful choice. Autonomous, sovereign individuals are free to act according to their own plan (6). The two authors believe that the respect for the autonomy of patients and their healthcare-related choices is one of the four fundamental principles of bioethics (5).
Assessed health technologies

Of the definition of health technology in the Romanian law (GD no. 8/2012 amending and supplementing GD no. 144/2010 regarding the organization and functioning of the Ministry of Health) for the present study we selected the following:

- a. drugs: insulin for insulin-dependent diabetic patients and antidiabetics for non-insulin-dependent diabetic patients;
- b. medical devices: self-monitoring blood glucose devices, glucometers;
- c. equipments and advanced medical techniques: insulin pumps;
- d. health policies, medical services and procedures, organization and management of health systems, including those covered by national health programs (GD 8/2012), in this case - the National Diabetes Program.

The primary focus was the ethical parameters in close connection with the related social issues.

MATERIAL AND METHODS

The assumed paradigm of social-constructionist research is that social reality is a product of negotiation between the interpretations of social actors. The research consisted in phenomenological analysis and symbolic interactions based on the study paradigm (2).

The nature of this research was exploratory given the novelty of this approach to the Romanian clinical and social context. The ethical assessment of medical technologies used in the care of diabetes patients relied on the following question: What is the role of medical technologies in developing the autonomy and responsibility of chronic patients? Individual interviews and focus groups were held in Iasi from June, 2011 to November, 2012. The criterion for selecting the participants was that of belonging to the target groups: family doctors or diabetes specialist, patients with type 1 (T1D) and type 2 diabetes (T2D), caregivers and other professionals involved in diabetes patient care (2). Both female and male individuals were selected. Participants were selected with support from Iasi Diabetes Clinic and Family Doctors Association, and invitation directly sent by the organizers to the focus group. Snowball sampling was taken into account: the interviewed suggested interviewing other significant people (2). Interviewed persons were allowed to fully express their ideas without exceeding the thematic focus until they finished what they had to say. Each interview lasted 40-50 minutes, being recorded with the consent of the interviewees, and then transcribed. Research was conducted in compliance with the principles of proper conduct in scientific research (Romanian Law 206/2004), in agreement with national and international research ethics documents.

Validity: Given the generative exploratory nature of this research, sampling had not in view the validity criteria specific to a quantitative study, but the completeness of quantitative information generated by saturating the sample. The sample was considered saturated when no responses appeared significantly different in the new interviewed subjects. The research consisted in a case study conducted in the Iasi County, where the only diabetes clinic in Moldova (the Eastern region of Romania) is located (2). Data validity is limited to the specific discursive universe of diabetes specialists, family doctors and diabetes patients in Iasi County, but with at least a nationwide extrapolation potential given the similarities in diabetes clinical practice.
RESULTS

Health behaviour is recognized, articulated and formalized into a major problem for public healthcare programs (2). The new meaning of the term is related to the description of autonomous individuals who can choose whether to act in response to a disease or to maintain health (2). Individual behaviours were analyzed with a less deterministic grid, emphasizing the capacity of individuals to act (7, 8), make choices, and be autonomous in health-related matters (9, 10).

In the last two decades the new approach to health behaviour depicts the patient as a person making autonomous choices about how to act or not to act in relation to his health (2). The approach evolved conceptually from the autonomy seen as central value by Kant, through Mill’s interpretation of autonomy as instrumental value to the modern theories on autonomy as authenticity, relational autonomy, informed consent, etc. (6).

A. Insulin and antidiabetic agents

Because chronic diseases require continuing medical care, they may raise the issue of care strategies effectiveness and of the balance doctor/patient involvement in the therapeutic process (12, 13). The participation of professionals and patients in the care process requires the patients to assume responsibility (14, 15), and care providers to provide information and autonomy support, as well as a collaborative process for optimizing long-term outcome (2, 16).

"First of all, when your glucose level was good all day, do you feel good because you succeeded, you could, you ate, you injected insulin, made exercise, and did everything right? You feel good on the inside, not necessarily ... This and that helped you a lot, I will try to do the same tomorrow, if I was able do it today why shouldn't I do it again tomorrow? And so, this motivates you the next day to succeed in achieving a good blood sugar level." (Diabetes patient)

Respondents highlighted the improvements in insulin therapy over the last years.

"During Ceausescu's regime, when injection tools were rudimentary, insulin was injected using glass syringes and Chinese needles that got calcium, tartar and needed to be boiled daily. I had to learn because I was explained that otherwise I could die. (...) The only complaint might be related to a specific punctuality (needed) for insulin injections. Sort of constraint." (Diabetes patient)

Overcoming many drawbacks related to how to self-administer insulin and eliminate its constraints was mentioned as a progress in insulin therapy. In terms of principilism ethics, we are talking about a deeper beneficence of this therapeutic form. In the absence of insulin type 1 diabetics may die relatively shortly, thus therapeutic compliance is mandatory. The degree of inherent discomfort is minimized by eliminating the need for a tools kit. Instead of glass syringes with metal needles that had to be sterilized, disposable needles are used.

"I never perceived it as a constraint, but unlike now, but there was a very large bag of tools; carrying a pot and syringes was not exactly comfortable nor enjoyable and people who didn't have medical information or medical culture looked somewhat strangely at you. It is true that not many people knew that I was a diabetic because the impact on a stranger could get me upset, and spoil my or his mood, too. I often avoided these things." (Diabetes patient)
The ease of today self-treatment and self-monitoring allows the diabetic patient a level of privacy in his social environment.

This approach of individual health behaviours, which emphasizes the social agent skills, has such benefits as reducing costs and decreasing the pressure on the healthcare system, empowering individuals and improving their health, but raises other problems. Increased responsibility for self-care assumed by patients raise specific challenges for those with multiple problems, such as worsening of a problem by treating others (2, 11).

Patients with chronic disease face a range of needs which change their lifestyle and usually lead to behaviours that promote physical and psychological wellbeing, which requires them to modulate their relationship with healthcare providers and to adhere to medical treatment, to monitor their health condition, to make care-related decisions, to manage the impact of the disease on their physical, mental and social functioning (2, 11).

B. Glucometer: self-monitoring and self-management of care

The interviewed physicians emphasized that self-monitoring devices are accessible and provided free of charge.

"You’d rather concentrate on self-monitoring devices, glucometers and test strips, nowadays prescribed free of charge to all insulin-dependent patients, which automatically is a big step forward compared to the years when I started residency, the patients having to make a financial effort. Maybe that is more relevant, I do not know" (Diabetes doctor).

From an ethical standpoint, free of charge self-monitoring devices are an implementation of the principles of beneficence and equity.

"(Regarding) technologies, if you want to know what is really relevant for the diabetic population, in my opinion the daily self-monitoring devices rank first. I think these are the most representative for the ordinary diabetes patient." (Diabetes doctor)

Relevant technologies are viewed in terms of accessibility to patients with median income, in terms of their capability to produce maximum improvement in as many patients. A technology is assessed by doctors according not only to its intrinsic medical value, but from an ethical and social perspective, that is from the perspective of beneficence and utility.

"They should be used with maximum efficiency. (....). Patients go home and eventually the tests expire and they do not use them. A patient came to me with a blood sugar meter and I saw he used it only three times in the last three months. So many test strips payed by the government are wasted; it is a waste of money on people who did not understand well what they got or they go and offer tests to their grandmother, friends, neighbour, priest in his village, and to the teachers and ... who knows who else, or they sell them." (Diabetes doctor)

Doctors discussed how technology is used by patients, insisting on the fact that the importance of this tool in diabetes self-management is not understood. This leads to waste of resources and, in the opinion of respondents, to unfair, unequal allocation.

"I have few diligent patients; they keep a daily record of their blood glucose levels. ... The normal blood glucose level is 100 (mg/dl), but they have 350, 400, 420, day after day, but never once went to ask
the doctor: "Look, my blood glucose is more than 4 times greater". Why do we give these people tests?" (Diabetes doctor).

Physicians underlined the importance of patient responsibility for his health condition focusing on the usefulness of free of charge prescription of blood glucose measuring devices in circumstances of misuse by the patient. They also believe that the use of glucometer, even if daily, is not enough. Knowledge on insulin dose adaptation to blood glucose level is also required; a diabetic patient unable to do that has to ask for medical help.

Also, diabetes patients understand the importance of self-management, taking control of their long term conditions and lifestyle.

"The doctor told me to do this test before I eat certain foods I know to cause an increase in blood glucose level and to see what happens. For example, boiled potatoes, for sure a potato dish will increase my blood sugar no matter how I cook it. She told me to check my blood sugar before I eat potatoes; first eat two potatoes and check for an increase (in blood glucose level), than eat one potato and also check for an increase. Well, I don't have the patience to do that" (Diabetes patient).

One of the interviewed physicians focused on patient opportunity to take control of their care process through frequent blood glucose measurements. This increases the degree of patient autonomy, giving him the chance to make informed decisions, and take responsibility for the decisions he makes.

"It is a minister's order and it says: one hundred tests; if it were my decision if a patient is disciplined, he deserves more tests, maybe 150 or 200; if the patient is not disciplined, I would give him only one box - 50 tests or I would give him nothing at al." (Diabetes doctor).

Inequity occurs between T1 diabetes patients - receiving free of charge blood test for blood glucose, and T2 diabetes patients who do not receive the same kind of gratuity. Inequity is also seen in patients suffering from other diseases not included in national programs.

"There are cases in which T2 diabetes patients who do not take insulin do tests more often than those with T1 diabetes (...) Inequity with other diseases, here there are so many things free of charge and the benefit for some patients is questionable. But heart failure is also a disease, and cirrhosis is a disease and nothing is free of charge in their treatment" (Diabetes doctor).

C. Insulin pump. Medical technology and responsibility for health

Insulin pump is considered cost-prohibitive by interviewed doctors, so they do not consider it relevant for assessing the ethics of technology used in diabetic care.

"If a diabetic comes up with the idea that he wants a pump. Let's see if the pump suits you. Insulin pump is not a device that replaces the pancreas and determines the insulin dose according to blood sugar level. I eat as much as I want and the pump does the job. No. And this device requires sometimes pressing a button, some adjustments. Thus, sometimes it's maybe harder to use a pump than having some already fixed doses of insulin" (Diabetes doctor).

The interviewed physicians considered that the difficulties the diabetes patients are faced with in order to follow an appropriate lifestyle in precarious financial conditions as a main public health problem; in this context of pauperism, technologies, even
the very advanced ones, if available at high costs, are irrelevant for care management and more, they can lead to a number of access-related inequities.

"I do not know if insulin pump is the best example of technology due to the fact that insulin pump is a very expensive device, and automatically prohibitive for most patients" (Diabetes doctor).

D. The National Diabetes Program

Diabetes was identified as the main cause of worsening the problems generated by chronic diseases. WHO statistics allow an estimation of the problem in Romania (2). Thus, in recent years there has been a marked increase in the prevalence of diabetes in Romania, with an almost 5-fold increase compared to the number of cases recorded during the two decades interval 1989 to 2009 (WHO/Europe, European HFA Database, data known to July 2010). Since 2006, Romania has a national diabetes program (Source: Diabetes - The Policy Puzzle, Country overview, Romania, 2008), technically coordinated by the “N.C. Paulescu” National Institute of Diabetes, Nutrition and Metabolic Diseases (2). This Institute coordinates the annual monitoring and prevention of diabetes complications, self-monitoring of diabetes patients, access to specific treatments, including insulin pump; the Institute is also the administrator of the National Diabetes Register.

"... let's take a bad example related to technologies: the patient may not realize, as in many other situations, that if something is given free of charge it does not mean that there is no financial effort behind what is offered to him, and I think this a problem with many of our patients. Maybe, sometimes we cannot explain quite clearly, maybe we cannot make ourselves understood, however that stuff costs something, but there is a degree of indifference to what is given free of charge." (Diabetes Doctor)

From an ethical standpoint, the National Diabetes Program is tributary to the utilitarian model of care.

"...creates a new type of addiction, because the diabetic patient becomes addicted to a right he does not use properly, as intended, and cannot be monitored outside medical units. What is he doing, how much is he really doing." (Diabetes doctor)

Respondents pointed out the risk of creating a relation of dependency on healthcare system instead of mobilizing patient’s resources to increase self-care management.

National Diabetes Program is considered absolutely necessary for patients, in the absence of free insulin their life being threatened. This Program also compensates patients’ socio-economic vulnerabilities.

"Let's hope it will not undergo changes ...otherwise... it would be a great misfortune, at least for those (patients) with type 1 diabetes, it will be disastrous if test will not be prescribed free of charge because only few have the financial means to buy their own tests." (Diabetes doctor)

The components of the National Diabetes Program are prevention and control of diabetes, insulin and oral hypoglycaemic agents being provided free of charge. According to the program, family doctors are responsible for the care of noninsulin-dependent diabetics, and diabetes doctors for the insulin-dependent patients. A check-up with the diabetes doctor is required every three months for each diabetes patient, being carried out in the county diabetes centres.

The interviewed doctors emphasized...
how important is the patients to be aware of the value of health technology and of the costs of freely provided devices and consumables through the National Diabetes Program.

Beside its medical objective, as underlined by diabetic patients, the National Diabetes Program also has a social dimension.

"At the end of the month, when all my pension money are spent and I have no more tests I go to the inpatient diabetes clinic ... because I have no more money to buy food. Do you believe me? It happened to me last month, and they also did blood glucose tests. I go there to get artificial feeding (intravenous glucose administration) because I have no money for food and if I do not eat I get into ketosis. I can live without food, but last month I lost very much weight, but now I am somewhat better. I have to eat at least once a day, they give me glucose and buffered insulin to avoid other complications, this doesn't seem normal to me." (Diabetes patient)

CONCLUSION

Our findings show that people with chronic illnesses develop autonomy through various relationships in the unique context of their life, social interactions, including mutual reactions of thoughts, feelings, concerns and habits, autonomy being negotiated during daily activities both in professional and family relationships (17).

As shown in the literature, the factors influencing patient autonomy are: health status/associated diseases (co morbidity); treatment; knowledge (about their disease); experience and skills; the personal way of approaching the disease; family patterns; type of relationships with others; history/life experience; social context (2,17). Self-management in diabetes (and other chronic diseases) relies more heavily on medical technology to monitor behaviour and/or biomedical parameters. These technologies are part of the psychosocial aspect of daily life (18).

Our study also shows that the patients suffering from diabetes mellitus have a high degree of autonomy given the type of treatment they receive and the possibility of disease self-management.

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