# Informed Consent in Medical Education: The Experience of The Medical Ethics Department of Ankara University Medical School \*

Tıp Eğitiminde Aydınlatılmış Onam: Ankara Üniversitesi Tıp Fakültesi Tıp Etiği AD' nin Deneyimi

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\*This article has been based on an oral presentation by the authors in 10th International Educational Technology Conference, Istanbul, 26-28 April 2010. This study aimed to develop a new method based on mastery learning in order to consider the subject of informed consent in medical education. As a professional skill, obtaining informed consent has been included in the third year curriculum of the Medical School of Ankara University, since 2004-2005 school year. Groups of 10-15 students in each using learning guides comprised the study population. The skill was evaluated by Objective Structured Clinical Examination (OSCE) using simulated patients, and the results of the examinations were analyzed. The results of OSCE demonstrated that 94% of the students exhibited a performance consistent with the principles of mastery learning regarding informed consent.

#### Key Words: Medical Ethics Education, Informed Consent, OSCE, Professional Skills

Bu çalışma, tıp eğitiminde yeterliğe dayalı öğrenim yaklaşımına göre aydınlatılmış onam eğitiminde yeni bir yöntem geliştirmeyi amaçlamıştır.Bir mesleksel beceri olarak aydınlatılmış onam alma eğitimi, Ankara Üniversitesi Tıp Fakültesi' nde 2004-2005 döneminden beri tıp fakültesi eğitiminin üçüncü yılında yer almaktadır. Eğitim; mesleksel beceri laboratuvarlarında, her 10-15 kişilik öğrenci grubuyla bir öğretim elemanının iki saatlik bir süreci eğitim rehberleri kullanmasıyla gerçekleştirilmektedir.Bu beceri,simule hastaların da kullanıldığı Nesnel Yapılandırılmış Klinik Sınav (NYKS) ile değerlendirilmekte ve sonuçları çözümlenmektedir. Burada yer verilen NYKS sonuçları öğrencilerin yeterliğe dayalı bir aydınlatılmış onam eğitiminde %94 oranında başarılı olduklarını göstermektedir.

Anahtar Sözcükler: Tıp Etiği Eğitimi, Aydınlatılmış Onam, NYKS, Mesleksel Beceriler

- Ethics is one of the important subjects taught in medical education. In this educational process, the place attributed to the subject of ethics and the teaching methods are inevitably multifold (1-4). It is essential for physicians to develop attitudes specific to their profession as well as having practical information and skills. This issue has been stressed in the studies of core curriculum in Turkey, as in other countries (5-7).
- Today, medical professionals are faced with various ethical issues in medical practice. Some of these involve classical values of medicine, and others, new headings created by scientific and technical developments. In this context, the physician-patient relationship, which is always a current issue and which is defined by the changes in physicians and patients' identities

as well as cultural and social changes, comprises an important ethical heading. Patient-physician interactions with regard to medical ethics is an important subject in the daily practice of medicine. Among these, the relationship between the physician and the patient is one of the most significant subjects. It is one of the issues, both ethical and legal aspects of which physicians should be familiar with and be able to reflect in their practice. There have been changes in the relationship between the physician and the patient throughout history. This has caused the emergence of new priorities. The fact that patients have gained a more equal status in their relations with physicians due to the questioning of the power held by medicine in social life and easy access to information are the main dynamics of this change. After World War II, the

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crimes against humanity committed by medicine have shaken the trust of people towards medical professionals. Hence, the tendency to control medicine has appeared everywhere through various applications (8). In addition to the measures taken for the inspection of medicine by institutions outside the relationship of the physician and the patient, real efforts have been made towards increasing the power of patients and raising their consciousness. The recognition of patient autonomy (which is in fact a concept of international law) and respecting it are the natural consequences of this trend. Formulation of the respect for autonomy as a target is a component that offsets the utilitarian approach of medicine and the attitudes supported by this approach. The counterpart of this argument in the practice of medicine is the concept of informed consent and its implementation. The only way to show respect for autonomy that is consistent with principles of medical ethics is to receive informed consent of patients. Medical schools have a role in the implementation of this practice through medical education as role models and in the consolidation of physician's attitude. Without a doubt, the importance of the faculty members who are role models for the students in the natural course of medical education is undeniable. However, medical schools do carry the responsibility to put additional emphasis on the issue of 'informed consent' within the context of formal ethics training. In Turkey, the majority of the problems experienced in the daily interactions between physicians and patients arise from lack of sufficiently clear and enlightening information provided to patients by physicians. Thus, providing future physicians the ability to obtain the informed consent of patients and families properly must be a priority of medical education.

Informed consent has become one of the most significant topics in medical education with respect to both daily medical practice and the process of research. It is generally defined as acceptance of the medical interventions by the patient who will undergo them after being informed about the content, risks, and benefits of the diagnostic and the treatment methods, and their alternatives. This has not remained as a verbal procedure; in Turkey, its documentation has become mostly obligatory.

Since obtaining informed consent has become one of the routine activities in medicine, it is necessary to add this subject to the medical curriculum (9-11). Due to some specific features of the cultural base in Turkey, such as paternalism and the health system problems, it is difficult for health professionals to learn the subject of 'informed consent' only through lectures. Our culture defines physicians as authoritarian and physicians are propped up in their position as the only determinant in the physician-patient relationship. There are also characteristics, such as the family council, problems in the functioning of the health care system, and lack of health insurance, which create a situation where "a service that is difficult to obtain is not questioned." This circumstance consolidates the physicians' paternalistic attitudes more firmly and creates a difficulty in the process of informing patients (12).

# Method

- Since 2002-2003 school year, Ankara University Medical School has no longer used the classic method of medical education. Instead, the school has adopted an integrated, modular, student-centered educational system. In this context in addition to classes lectured, new methods were introduced in ethics education in all the medical courses. The new method was implemented in small groups of students by the Deontology Department using case discussion, education guides, and Objective Structured Clinical Examination (OSCE).
- The skill of obtaining informed consent was included in the curriculum of Ankara University Medical School in the

academic year of 2004-2005. The difficulties mentioned above were taken into account by the academic staff of the Medical Ethics Department while developing the method of practice. It was conducted as skill training in the Professional Skill Development Laboratory.

- The study population consisted of 137 students in the third year of medical education, who received training in groups of 10-15 for two hours in each group. A faculty member from our department provided brief theoretical information on the subject beforehand, and ten sample cases were discussed with student groups using previously prepared learning guides (Table 1). Thus, including the reinforcement of information, the education sessions lasted about four hours for each group. The manual that includes cases collected from various countries by UNESCO was previously translated into Turkish and printed as an education material (13). Among the samples selected, in particular the skill of obtaining informed consent in varying situations was underscored. Some preset situations such as informed consent before a surgical procedure (case 1) and informed consent before prostatovesiculectomy (case 2) were chosen from this book and used as illustrative cases for education. In the educational process, the method of obtaining informed consent was emphasized throughout the discussions held with and by the students. In these small group discussions, the students played the roles of both patient and physician, while the other students were observers. Thus, simulated patients were not used during the educational process. Patients who were simulated as much as the technical and financial conditions allowed worked on the day of the examination only.
- OSCE is an evaluation technique that is used for competency based education processes. According to complete learning basis, the student learns a skill in a stepwise fashion, using a checklist, and the student is expected to perform

the skill without skipping any of the steps. Skill training is done with this method in all the other areas; a skill related to Otolaryngology or Urology is also taught using models that are similar to those used in ethics education. Different skills of OSCE students are evaluated through an OSCE examination, all parts of which are held on the same day . will discuss the treatment options with your patient.

Option I: Performing total radical mastectomy, which is excising all the breast tissue, axial lymph nodes and a part of the pectoral muscles and then administering chemotherapy. Its advantages are minimizing the risk of recurrence and obviating the need for radiotherapy. Its disadvantages are swelling in the

Table 1: Learning guide for obtaining informed consent

Steps of skill	Yes	/ No
Introducing oneself		
Informing the patient about the procedure to be performed		
Explaining the rationale of the procedure		
Explaining the expectations about the benefits		
Explaining the risks		
Informing the patient about the other options		
Checking whether the information provided was understood		
Repeating with one's own words		
Asking if the patient consents		

- After teaching how to obtain informed consent, a new case study is prepared for the end of every module and the student tries to perform this skill within 10 minutes with another student simulating the patient. During the OSCE examination, a faculty member monitors the students using a checklist and assigns grades.
- In the OSCE exam, new cases were prepared, simulated patients were trained and assessment guides that were developed for this skill were used.
- The score of station one, which is the place of informed consent skill, was determined as 10 and the results of the examination were evaluated in median and percentages (Table 2).

# Examination case

- "Mrs. H. is a 55 year- old female patient with two children. One of the children is at the university and the other attends high school. A solid mass with a diameter of 5mm was detected in her right breast. Biopsy results turned out to be malignant. Ultrasonography revealed no pathological findings in axial lymph nodes.
- As a physician, you talked about your diagnosis with your patient in your previous meeting. In this meeting, you

arm due to the sluggish lymph flow, restriction in arm movements and complete loss of the breast. Option II: Breast preserving tumor excision that is removing the tumor along with the adjacent tissue, subsequently undergoing chemotherapy and radiotherapy. Its advantages are the conservation of the breast with no effect on the lymph flow and arm movements. Its disadvantages are higher risk of recurrence, and side effects of radiotherapy (burn and other negative consequences that may be caused by radiation).

"Exercise the skill of obtaining informed consent by presenting the options to your patient".

# The results of OSCE

Based on the results in this table, it is clear that students have been successful in developing this skill with a mean of 9.54 and a median of 10.

**Table 2:** Objective structured clinical examination- descriptive statistical data of the skill of obtaining informed consent



The number of students	137
Mean	9.54
Median	10
Mode	10
Standard Deviation	.946
The coefficient of skewness	-2.489
The coefficient of kurtosis	6.053
Minimum	5.63
Maximum	10.00

Modular system does not offer an individual opportunity for evaluation of IC training. Therefore, it had to be represented in quantity. However, the students expressed during both the education sessions and reinforcement sessions that the method used was more effective than the method used in classical education system and that it was much easier and possible to empathize with the patients. Perhaps, it will be helpful to provide examples of such statements since each is important in quality but has no chance of being internalized within the system:" I had never thought of that before", "preoperatively, patients should be informed as to how carrying a colostomy bag ill affect daily life", "we have to be understandable to our patients whether they are illiterate or well-educated.", " we have to examine numerous patients within a short timeframe in the outpatient clinics, but this does not necessarily mean we should not inform them"

# **Discussion and Conclusion**

- In the classical system of education in our school, medical ethics was a third year, one-semester must course. It took only 16 hours and its content was organized to proceed from general concepts to special topics. The program was mainly based on lectures and partly supported by role-playing for a class of approximately 120 students. With this method, the integrity of the subject could be conserved and systematic approach was not lost. However, it was not possible to work in small groups with this faculty-centered approach, which harbored other disadvantages of the theoretical lessons (14).
- Core curriculum studies have been carried out to render medical education more functional, integrated and

community-based. In the course of these studies, professional skills and attitudes that should be achieved with medical education have been established as learning targets (7). Based on this primary study in the 2002-2003 academic year, the classical system has been replaced by a new education system, which is integrated, studentcentered, and competency-based. In the process reorganizing six years of medical education, the preparations for the third year has just been completed. The timing, context, and the teaching method of the subjects in medical education have not yet been completely determined. In this paper, initial observations and the results obtained with third year students have been presented in the context of the medical ethics education.

Working with small groups and learning by doing during the practice of obtaining informed consent yielded favorable results. Working with small groups has been advantageous for the tutors as they were able to observe the communication skills of the students and how they use their native language. It is also possible to receive immediate feedback from the students. It was clearly seen in the OSCE examination that this approach had a positive effect on learning, and the majority of the students were successful in the exam. This could be the draft for another study comparing the effects of different methods of education and evaluation by providing this education through lectures involving multiple choice test evaluation in the classical system. There were a few problems with the method; namely, the number of cases was high for the time allotted for this practice; thus, the students found it hard to focus on the discussions because of repetitions and the inadequacy of a single tutor in following all the groups. The questions and the explanatory information

attached to the cases sometimes misled the students, and they lost their focus on the subject. However, these limitations may be compensated for with observations and feedback, and this method can be improved. Literature shown us, similar methods have been developed to evaluate the professionalism of medical students (15). Currently, this education is continuing in the third year at Ankara University Medical School. The results of the first vear that are the subject of this article were used as a guide for more functional education, and it was simplified by decreasing the number of cases.

By means of this method, the student gains awareness of the solution of ethical problems as well as developing the skill of obtaining informed consent. The reflection of informed consent education onto clinical medical education warrants the integrity of ethics education. In order to gain this skill, students have to grasp the thinking mechanism underlying this approach and then need to pass through a process of skill training including the steps of observation, analysis, implementation under control, discussion, and feedback. The skill of obtaining informed consent encompasses cognitive skills such as formatting the information content on the relevant situation, evaluation of competence, and attitude skills such as imparting authoritative information and protecting the patient's right to choose. Therefore, it is imperative to develop communication skills and to implement attitudeforming techniques in addition to offering information on medicine.

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