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Management of Consent Elasticity in Gastrointestinal Procedures

Gastrointestinal Prosedürlerde Onam Esnekliği Yönetimi

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ABSTRACT Not being able to provide informed consent with a competent decisional capacity put the productive patient-doctor relationship at stakes. Although, decisional capacity is not a binary, all-or-nothing phenomenon, it is up to the physicians to decide on behalf of their patient whether they opt in or out of autonomy. The objective was to explore this dilemma in medical ethics and analyze the issue of consent-elasticity under the medico-legal system in Turkey. A representative quota sample of 15 adults hospitalized for gastrointestinal diseases with impaired decisional capacity were included. From a legal/ethical point of view, a 5-layer model of risk stratification have been proposed and 3 best representing cases were matched with each level. In Turkey, the statute of patient rights and Oviedo Convention explain the circumstances under which informed consent can be waived in adult patients. Related terms from these legal measures set the tone for the model in the management of consent elasticity. The doctor-patient concordance decreases as the degree of risk increases and the tendency to seek a regulatory mechanism for mediation in crisis resolution becomes even more evident. The model creates a basis for structured management of consent-elasticity in gastrointestinal procedures and secure the shared decision making and doctor-patient concordance. Yet when a high-risk situation is identified and the clinical strategy appears to be backfiring, consulting the bioethics committee, the administrative person or body and sometimes a colleague is a reasonable and a highly efficient way to elucidate the ethical norms relevant to the case.

Keywords: Informed consent; shared decision making; medical ethics

ÖZET Sağlıklı karar verme yetisi olmayan hastanın aydınlatılmış onam verememesi, verimli hasta-hekim ilişkisini risk altında bırakır. Karar verme kapasitesi, akla kara gibi seçilecek ikili bir fenomen olmasa da, bir hastanın otonomi için uygun olup olmadığına hastası adına hekim karar verir. Çalışmanın amacı bu ikilemin tıp etiği açısından araştırılması ve aydınlatılmış onam esnekliği konusununun Türk Tıp Hukuku mevzuatına göre analiz edilmesidir. Çalışmada gastrointestinal hastalıklar nedeniyle yatırılan, karar verme yetisi olmayan 15 erişkin hasta, kota örnekleme ile seçilmiştir. Hukuk ve etik açıdan hekim-hasta etkileşimindeki risklerin ortaya konması için 5 seviyeli bir model önerilmiş ve her bir seviyeyi en iyi temsil ettiği düşünülen 3 vaka ile eşleştirilmiştir. Türkiye'de hasta hakları yönetmeliği ve uluslararası Oviedo anlaşması, erişkin hastalarda aydınlatılmış onamdan feragat edilebilecek koşulları açıklamaktadır. Onam esnekliği yönetiminde standartların belirlenmesine imkan verecek olan model, bu yasal metinlerdeki ilgili maddelerden yola çıkarak hazırlanmıştır. Risk derecesi arttıkça doktor-hasta uyumu azalmakta ve aradaki krizlerin çözümlemesinde, arabuluculuk için düzenleyici bir mekanizmaya olan ihtiyaç daha belirgin hale gelmektedir. Model, gastrointestinal prosedürlerde onam esnekliğinin yapılandırılmış yönetimi için bir temel oluşturmakta ve ortak karar verme süreci ile doktor-hasta uyumunu kuvvetlendirmektedir. Yine de, yüksek riskli durumlarda klinik strateji ters gitmekteyse biyoetik komitesine, idari birim ile hastane yöneticilerine veya bazen bir meslektaşa danışılması vaka ile ilgili etik normların açıklığa kavuşturulması için makul ve etkili bir yoldur.

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Anahtar Kelimeler: Aydınlatılmış onam; ortak karar verme; tıp etiği

A good professional judgment in a medical exam begins with an analysis to decide whether the patient is competent enough to understand simple and rational concepts and make deliberate choices. Although decisional capacity is not a binary, all-or-nothing phenomenon, it is up to the physicians to decide on behalf of their patient whether they opt in or out of autonomy legislation as per the binding directives of the legal system they are in. When considered competent and opted in for autonomy the patient must be adequately informed and not coerced during the process of informed consent for a beneficial medical intervention.[1]

Respecting the four ethical principles of Beauchamp and Childress-autonomy, non-maleficence, beneficence and justice- have been the dominant approach to the evaluation of dilemmas in medical ethics.[2] Properly obtained informed consents respecting these principles would ensure that patients are fully informed and protect the physicians from litigation in the event of a complication. However, it is a matter of interpretation how these principles are put into practice-given circumstances where these principles conflict and the most important one takes priority.[3]

On the other hand, not being able to provide informed consent with a competent decisional capacity for a medical intervention may expose the doctor-patient interaction/relationship to fragile conflict issues and put the healthy and productive relationship at stakes. Cases of this sort are not very infrequent and warrant clinical research and evidence-based practice as they are likely to have increased medicolegal significance given their potential to identify controversial practices. To this end, one of the most vulnerable group of patients for ethical dilemmas and legal conflicts regarding the individual autonomy and self-determination is the elderly people.[4] Other groups vulnerable for autonomy related ethical problems are patients with severe psychiatric illnesses, physical disabilities, loss of consciousness and patients requiring urgent intervention.[5] In this regard, there is a need to increase the number of studies on "Informed Consent" examining different patient-physician groups in our country where the paternalistic approach is evident in the patient-physician relationship.[6]

MATERIAL AND METHODS

The issue of elasticity in the consent process is analyzed through challenging surgical cases. From a legal and an ethical point of view, a 5-layer model of risk stratification for doctor-patient interaction have been proposed (Figure 1) and 3 best representing cases were matched with each level in this framework to scrutinize the degree of elasticity.

Approval was obtained from the institutional ethics committee. The study respects the ethical standards in the Helsinki Declaration of 1975, as revised in 2013, as well as the national law.[7] All personally identifying details have been edited to ensure that confidential information is not disclosed. A representative quota sample of 15 adults hospitalized for gastrointestinal diseases with impaired decisional capacity to consent, were included to examine controversial medicolegal practices across the layered model of risk stratification for doctor-patient interaction. Thus, authors recruited sample members through a retrospective documentation review of de-identified weekly performance lists of emergency operations, records of patients with additional diagnosis of a psychiatric illness and records of patients with discrepancies between preoperative and postoperative diagnoses. Documentation review included adult patients hospitalized for gastrointestinal diseases in the general surgery departments of a tertiary care facility (Akdeniz University Hospital, Antalya) from March 2011 to August 2016 and a secondary care facility (Palandöken State Hospital, Erzurum) from August 2016 to October 2017.

Power analysis was calculated on the basis of a hypothesis that there will be two opposite risk groups of treatment delay due to consent elasticity; lowest possible risk group will result in <1% treatment delay and highest possible risk group will result in >90% treatment delay. The alpha level for rejecting the null hypothesis was set to 0.05 and sample size of risk groups was calculated to be 3.

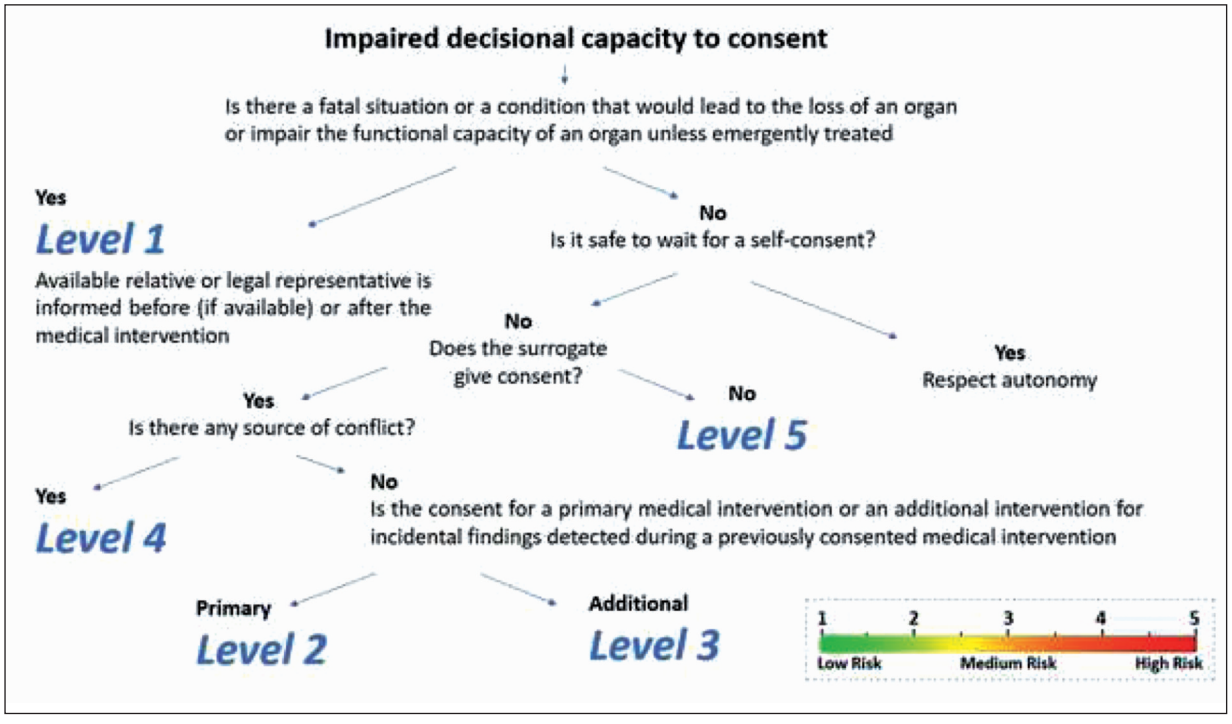

FIGURE 1: Layered model of risk stratification for doctor-patient interaction in the presence of impaired decisional capacity.

RESULTS

LEVEL 1

24-year-old male was admitted to emergency room (ER) after a motorcycle accident and intubated upon arrival. He had traumatic amputation under the left knee, head trauma and a perineal and full-thickness anal sphincter injury. No relatives were around and the patient was rushed from the emergency department to the emergency operation theatre without an informed consent. After hemostasis, anal sphincter was repaired and an end colostomy was performed for complete fecal diversion.

22-year-old male was admitted with lower right quadrant abdominal pain suggestive of acute appendicitis. Consent for laparoscopic appendectomy was obtained from the patient and he was taken to laparoscopic appendectomy. At the operation, the appendix was found to be normal but there was purulent collection occupying the entire right paracolic space and the Morrison's pouch. Exploratory laparoscopy revealed a perforated prepyloric ulcer and Valentino's syndrome was diagnosed. After conversion to laparotomy the patient underwent primary closure, covered by Graham's patch. Patient and the family were informed after the operation.

34-year-old female was admitted with incarcerated inguinal hernia. After unsuccessful bedside reduction attempts she was taken to operation. Unilateral ovary, fallopian tube and a small segment of omentum were appeared to be strangulated and necrotic inside the direct hernia sac. She was evaluated by obstetrician/gynecologist and unilateral salpingo-oophorectomy was performed along with a segmental omentectomy after obtaining an intraoperative consent from her spouse who stressed the point that after years of trying fertility drugs, insemination procedures, and traditional in vitro fertilization (IVF), the couple have failed to have a baby and have applied for an adoption order. Next, the hernia was repaired without using mesh.

LEVEL 2

82-year-old male with dementia and an old history of peptic ulcus related surgery was admitted with diffuse abdominal pain, weight loss and constipation. He had been hospitalized several times for at-

TABLE 1: The selection of patients for risk-sharing groups and the tendency to seek a regulatory mechanism for mediation in crisis resolution.

		Reason for match	Delay in treatment	Consultation	Impact of consultation	Ethical Comments
1	Level 1	Fatal risks: Fecal contamination, sepsis Functional risks: Anal sphincter failure	No	No	-	Fecal deviation enhanced the sick leave period in this patient who lost his extremity
2	Level 1	Fatal risks: Intraabdominal sepsis Functional risks: Parenteral feeding	No	No	-	Discrepancy between radiologic and surgical diagnosis is a very frequent issue in medicine. Patient appreciated his clinical situation when Valentino Syndrome clearly explained to him
3	Level 1	Fatal risks: Intraabdominal sepsis Functional risks: Infertility	No	Obstetrician - gynecologist consultation	Spouse was informed about the fertility issue to make his decision	Although this patient already has infertility problem, this patient still had her contralateral ovary and tube with some potential for fertility
4		Not safe to wait for autonomy: Recurrent attacks of subileus points to a complete obstruction or an aspiration risk in the long run	Minimum (1-2 hours)	Psychiatry and neurology consultation	Family and patient were informed about the multifaceted clinical course	Multidisciplinary risk assessment helped in decision making
5	Level 2	Not safe to wait for autonomy: Autonomy is limited and incarceration risk outweighs	No	No	-	Mental retardation was well defined in this patient and no other clinical measure was taken to increase autonomy other than social support
6		Not safe to wait for autonomy: Possible mental fluctuations warrant a legal representative to be invited to the decision making	No	No	-	Patient was followed up in psychiatry outpatient clinic and she looked reasonable. Yet, her consent alone might be legally controversial.
7		Not safe to wait for autonomy: Anticipated postoperative bowel edema and adhesions would restrict an early oncologic surgery	No	Colleague	Professional secondary opinion strengthened the decision making	A short conversation or even a brief telephone conference with experienced colleagues could be a highly efficient way to elucidate the ethical norms in surgical dilemmas
8	Level 3	Not safe to wait for autonomy: Migrated plug mesh (incidental finding) was risking a bowel wall injury.	No	No	-	Maintaining abdominal wall integrity to avoid a bowel injury are a part of unspoken consent. Yet, a surrogate consent will assure a healthier patient-doctor relationship.
9		Not safe to wait for autonomy: Malignant looking ileal mass possibly causing high NSAID consumption (and duodenal perforation) indicated a bowel resection.	No	Colleague	Professional secondary opinion strengthened the decision making	Although the possible need for a stoma is included in written consents for many abdominal operations, this is not always discussed comprehensively with the patient preoperatively. Thus, a surrogate consent is indispensable
10		Conflict: Patient was refraining from autonomy and possibility of a complication was annoying his surrogate	Moderate (2-3 hours)	Colleague	Pros and cons of a tertiary referral were discussed	Patients and families should be warned that although tertiary referral seems a reasonable option in surgical complications, losing time during the transfer may not be in the best interest of the patient.

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TABLE 2: continue.

	Reason for match	Delay in treatment	Consultation	Impact of consultation	Ethical Comments
Level 4					
11	Conflict: Irrational and fluctuating mental status was impairing decision making capacity and the family members were inclined to coerce for the operation	Significant (1-2 days)	Psychiatry consultation	Surgical operations sometimes may unveil an anxiety disorder.	Fluctuating mental status impairing decision-making capacity for an elective surgery warrants a psychiatry consultation. Moreover, this was more than a simple preoperative anxiety.
12	Conflict: "No stoma" advanced directive of a geriatric patient overruled by her family	Minimum (1-2 hours)	No	-	Expressing the facts about her medical condition and encouraging patient and the family to discuss their values helped reducing the conflict and break down the stoma prejudice.
Level 5					
13	Surrogate refused ileus treatment and wanted to bring the patient to another hospital	Severe (>2 days)	Administrative person	Hospital insurance policies were discussed.	Insurance may not cover the transfer if a surrogate wishes to change hospital for personal reasons. Informed refusal should include the risks of transportation without an ambulance.
14	Surrogate refused elective colostomy	Severe	Colleague	Professional secondary opinion was obtained	Informed refusal of colostomy should include the increased risk of occasional relapsing attacks of pseudoobstruction in dementia.
15	Surrogate refused donation	Severe	Transplant coordination team	The family organ donation interview was conducted.	A standardized professional family interview conducted by staff of the transplant coordination team is essential in order to increase donation rates.

tacks of subileus. His last bowel movement was two days prior to admission. Clinical and radiological findings were suggestive of mechanical partial small bowel obstruction at the terminal ileum. The patient was taken to diagnostic laparotomy with the consent of himself and his daughter. Diagnostic laparotomy revealed an incarcerated Petersen space hernia arose after the antecolic Billroth II gastrojejunostomy. Incarcerated segments were reduced. There was no need for a segmental bowel resection as there was no irreversible ischemia and the Petersen space was closed with interrupted slowly absorbable sutures.

30-year-old male with a known history of pica syndrome not associated with a nutritional deficiency state but mental retardation, presented to outpatient general surgery office with complaints of occasional constipation and a bulging under the scar of a previous abdominal incision from an emergency extraction of a bezoar via gastrotomy after eating vinyl tablecloths. Since then, he has been followed up at the psychiatric outpatient unit. His mother denied any knowledge of him sustaining the disordered eating behavior. Clinical and radiological findings were consistent with an incisional hernia. He was taken to hernia repair with the consent of himself and his mother.

37-year-old female who has been treated for schizophrenia for about 10 years was referred to outpatient general surgery office with complaints of painful and bloody bowel movements. She was diagnosed with grade IV internal hemorrhoidal disease. Nonsurgical treatment failed and hemorrhoidectomy was performed with the consent taken from the patient herself and her mother.

LEVEL 3

56-year-old overweight female presented with an umbilical lump, occasional abdominal distension and a new onset right upper quadrant abdominal pain after fatty meals. A mild tenderness in the right upper quadrant and a reducible hernia in the umbilicus were elicited on

palpation. Ultrasound demonstrated multiple gallstones and a 1-cm defect in the umbilical fascia. CBC/biochemistry/urinalysis excluded any inflammation or biliary tract obstruction. Patient was offered but did not participate in any opportunistic cancer screening except for breast cancer. She was then scheduled for an elective laparoscopic cholecystectomy and simultaneous umbilical hernia repair. Incidental rectosigmoid colon cancer invading uterus was detected during the procedure. The patient's spouse, intraoperatively informed, gave consent for additional interventions. Cholecystectomy, anterior resection with stapled colorectal anastomosis (without ileostomy), hysterectomy and primary umbilical hernia repair were performed.

84-year-old male with Alzheimer's disease and a history of left sided inguinal hernia repair was admitted with abdominal distention. It was difficult to communicate with him. He had diffuse abdominal tenderness. Pneumoperitoneum was seen under the diaphragm on chest X-ray. Computed tomography confirmed the free air and revealed a substantial amount of periintestinal fluid collection. Informed consent was obtained from his son and on diagnostic laparotomy for gastrointestinal perforation, pneumatosis intestinalis was observed on the small bowel segments liberated from the matted adhesions in the lower left part of the abdominal cavity. Adhesions and fluid were most likely secondary to the inflammatory reaction against a plug mesh partially migrated towards the lower left paracolic gutter and protruding like a stalactite hanging down obliquely from the inguinal ring. The son was informed and adhesiolysis and plug mesh rearrangement were performed.

56-year-old male with severe diffuse abdominal pain had tachycardia, absent bowel sounds, involuntary guarding and rebound tenderness of the abdomen. Pneumoperitoneum was seen under the diaphragm on chest X-ray. Computed tomography confirmed the free air and mostly perihepatic fluid collection. Informed consent was obtained from the patient and he was taken to diagnostic laparotomy for gastrointestinal perforation. Duodenal peptic ulcus perforation was sutured primarily and covered by Graham's patch. Another lesion found on exploration was a 10x15 cm mass encompassing ileal segments while creating abrupt angulations which were partially obstructing the bowel lumen. His son was informed about the lesion and consent was obtained for additional small bowel resection and double-barrel ileostomy.

LEVEL 4

21-year-old male was admitted with the diagnosis of acute appendicitis. He subsequently underwent a laparoscopic appendectomy. On the postoperative day 3, deterioration in his clinical condition despite intensive antibiotic treatment was indicating an emergency "second look" laparotomy for diffuse intraabdominal sepsis. Although CT scan excluded any leakage, patient and family informed about the possibility of a complication. The patient left it to his sister to make the decision because she was a nurse and he was not feeling competent enough. His sister said it appears that there was a mistake made somewhere and the patient should be transferred to a higher level of care. The sister was notified that transferring the patient to another hospital might not be in the best interest of the patient; after all, a delay in treatment to control the infectious source and to purge bacteria and toxins would likely have a detrimental effect on the outcome. Informed consent was obtained (from the patient and the sister) for second-look laparotomy, peritoneal irrigation and debridement which ultimately worked out well.

42-year-old male with right sided reducible indirect inguinal hernia consented for the procedure and he was taken to the operating room. As the nurse started to put a needle into his arm, he started to shake and cry with regret and said he had changed his mind and was pleading to go home. The procedure was halted although his wishes were perceived as irrational and fluctuating; at the moment when he was taken out of the operating room, he apologized for what he was doing and begged for turning back to the table. He exhibited the similar regressive behavior next operating day but this time even after 1-mg preoperative lorazepam. Although his close relatives were inclined to coerce for the operation, the procedure was

halted again and a psychiatric referral was planned as an anxiety disorder impairing decision-making capacity was suspected.

78-year-old lady with incarcerated femoral hernia was warned that a bowel resection and a temporary stoma were very likely. She certainly did not accept any stoma. It was then explained to her that delaying or abstaining from a stoma in certain conditions run the risk of confronting many complications which may end up with much more difficult decisions than a stoma. After expressing the facts about her medical condition, she pulled back her "no stoma" advanced directive and designated her daughters as the next-of-kin surrogates for the stoma decision. Ultimately, a temporary double barrel ileostomy was created after the removal of a necrotic ileal segment, as per the intraoperative consent obtained from her daughters.

LEVEL 5

85-year-old female patient with Alzheimer's disease and complaints of a distended abdomen, and occasional nausea/vomiting had not passed flatus for the last 3 days and had lost weight lately. Bowel sounds were hypoactive, rectal vault was empty. Abdominal CT, showing peritonitis carcinomatosis of unknown origin and accompanying omental cake appearance, and upper gastrointestinal endoscopy revealed findings compatible with advanced gastric cancer but it would take at least 2 weeks for the pathology results. The next-of-kin were informed verbally about the strategy. That included parenteral feeding for a while and, should the ileus symptoms persist in spite of the usual ileus treatment, a diagnostic laparotomy for intestinal obstruction with a possible surgical placement of an enteral feeding tube. They refused the strategy and stated that they wanted to bring her to another hospital.

92-year-old female patient with a late-stage dementia, presented to ER with massive abdominal distention and fewer. Bowel sounds were hyperactive. Rectal vault was full. Plain abdominal radiography revealed massive colonic dilatation in all segments. Acute colonic pseudo-obstruction was diagnosed. There was a history of multiple hospital admissions with similar episodes. She was monitored with manual disimpaction and enemas. Complete decompression was succeeded after three days of conservative treatment strategy. However, elective colostomy was recommended to minimize the risk of bowel perforation, but her relatives refused.

42-year-old male was on acute liver failure and had a life expectancy of less than 7 days without a liver transplant. The diagnosis of brain death was declared in another 30-year-old patient in the intensive care unit. He was a potential organ transplant donor but his family refused donation.

The selection of patients for risk-sharing groups and the tendency to seek a regulatory mechanism for mediation in crisis resolution are scrutinized in (Table 1).

DISCUSSION

It is imperative that physicians should be familiar with the laws of their country regarding informed consent process. The European Convention of Human Rights and Biomedicine, (hereinafter the Oviedo Convention), sits at the top of the hierarchy of norms in Turkish legislation which regulates the informed consent process.[8] The Convention was adopted by the Turkish Grand National Assembly in the name of the "Law Concerning the Protection of Human Rights and Human Dignity in Terms of Biology and Medical Practice: The Law for the Approval of Human Rights and Biomedicine Agreement" on December 3, 2003, and enacted by law number 5013; entered into force after being published in the official journal of the country, *T.C. Resmi Gazete*.[9]

Chapter 2 in The Oviedo Convention focuses on consent and Article 6 in the chapter specifically stipulates the rules for the protection of persons not able to consent. Accordingly, an intervention for direct patient benefit, may only be carried out with the authorization of his or her representative or an authority or a person or body provided for by law; and the authorization may be withdrawn at any time in the best interests of the patient. Paragraph 3 in the Article 6 stresses that the individual concerned shall as far as possible take part in the au-

thorization procedure. Article 7 on the other hand maintains that any medically necessary intervention may be carried out immediately for the benefit of the health of the patient when appropriate consent cannot be obtained because of an emergency situation.

Another regulation in the Turkish legislation, which has a legal context with respect to informed consent is the statute of patient rights.[10] The statute clearly explains the circumstances under which informed consent can be waived in adult patients. Article 24 in chapter 5 stipulates that the power of attorney of a patient with restricted legal capacity has the power to consent to a medical intervention given the patient is involved in the process as much as possible. However, in the lack of or non-attendance of power of attorney or when this patient is unable to express his or her own wishes no consent is required. In cases where the power of attorney refuses to consent, that medical intervention is subject to court decision in accordance with Articles 346 and 487 of the Turkish Civil Code.[11] The article 24 also emphasizes that the legitimate advanced directives of patients should all be taken into account. And no consent is required if the patient is incompetent to make health care decisions in the presence of an emergency vital situation or a condition that would lead to the loss of an organ or impair the functional capacity of an organ. In such cases, the patient's available relative or legal representative is informed before (if available) or after the medical intervention. During a consented intervention, Article 31 in the chapter vests the physicians with a measure of flexibility should extending a medical intervention beyond that to which there was consent is necessary to prevent the loss or functional impairment of an organ. As a matter of fact, if the patient is competent to make health care decisions in the presence of an emergency but refusing to consent, an informed refusal should be properly documented as per the Article 26; and if the patient does not sign the refusal, an official report is written and filed.

Related terms from these legal measures set the tone for the model to allow for standards to be set in the management of consent elasticity. The doctor-patient concordance decreases as the degree of risk increases and the tendency to seek a regulatory mechanism for mediation in crisis resolution becomes even more evident (Table 1). On the other hand, the patient selection in this study uses representative quota sampling method which does not utilize random selection. Thus, it is impossible to determine the possible sampling error and it is very likely that the selection is based on ease of access and cost-effective considerations and resulted in sampling bias. This strategy was a limiting factor in the study that, it is impossible to make statistical inferences from the sample to the entire population. Because of the retrospective design of the study some important ethical characteristics were not recorded. Studies with prospective design should be considered to validate the current findings.

Informed consent is a shared decision-making process with patients and/or their surrogates. To improve surgical consent, Bernat and Peterson suggests conceptualizing consent as an ongoing bidirectional process of communication, education, question answering, and listening with the patient or surrogate that proceeds through the continuum of care.[12] In cases with clinical ethics conflicts, well-trained competent bioethics consultants should play a critical role.[13] Traditionally a bioethics consultant would be the mediator between the disputants and struggle to ensure that resolutions fall within medical "best practice" guidelines; yet the consultant must shift the discussion to either an institutional bioethics committee or a properly empowered administrative person or body if the struggle fails.[14] In Turkey, only tertiary care facilities employ bioethics committee. In lower level care facilities, only the administrative person or body plays this mediation role.

CONCLUSION

The risk stratification model presented in this paper, creates a basis for structured management of consent-elasticity in gastrointestinal procedures and secure the doctor-patient concordance. Trying to cope with consent elasticity alone, may look like

the easiest way out. However, this is for sure not the best idea. Inviting a colleague to collaborate in the shared decision making process would be a moral and practical strategy. If conflicts are still inevitable, a mediation plan with additional parties is warranted. Thus, when a high-risk situation is identified and the clinical strategy appears to be backfiring, consulting the bioethics committee, the administrative person or body is a reasonable and a highly efficient way to elucidate the ethical norms relevant to the case.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

All authors contributed equally while this study preparing.

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