

January 2005

Uninformed Consent

Edwidge Jourdain Thomas ANP, Dr.NP
Columbia University Medical Center

Follow this and additional works at: <https://aquila.usm.edu/ojhe>

Recommended Citation

Thomas, E. J. (2005). Uninformed Consent. *Journal of Health Ethics*, 2(2). <http://dx.doi.org/10.18785/ojhe.0202.06>

This Article is brought to you for free and open access by The Aquila Digital Community. It has been accepted for inclusion in *Journal of Health Ethics* by an authorized editor of The Aquila Digital Community. For more information, please contact aquilastaff@usm.edu.

Uninformed Consent

Edwidge Jourdain Thomas , ANP, Dr.NP
Columbia University Medical Center

Abstract

Patients seek the advice of health care providers regarding treatment options and protocols. When there is a condition with several treatment alternatives, patients generally rely on their health care providers to explore all the options available and guide them on the evidence-based treatment that would ensure the best outcome. This simple premise is complicated by the fact that there are often not one, but a range of treatments with differing interpretations of the best outcome. In addition, failure to ensure that patients have adequate comprehension of treatment options and complications often result in negative treatment outcomes. Cases where the treatment causes more harm than the disease generally lead to debates of whether observation without intervention is the optimal course. This article discusses a patient's total reliance on the advice of the attending physician, who apparently failed to ensure that the patient had adequate comprehension of the long-term implications and complications resulting from a recommended surgical procedure. The ethical dilemma that emerged is analyzed, with emphasis on the concept of informed consent, by reviewing the patient's surgical outcome and roles of the surgeon and primary care provider. The paper concludes by providing recommendations to ensure that patients are sufficiently informed before consenting.

Keywords:

Informed Consent, Pancreactectomy, Ethical Principles, and Physician-Patient Consent

Uninformed Consent

Case Report

A middle-aged, English-literate, African widow with two school-aged children, temporarily assigned as a foreign office worker in the United States, visited a primary care practice for medical care during her tenure. A month earlier, she had been diagnosed with hypertension and type-2 diabetes during a pre-employment physical examination. Her past medical history was remarkable considering a benign pancreatic mass was found on routine physical examination five years ago. Upon presentation, she was asymptomatic and showed no clinical evidence of complications. The physician advised her to maintain regular careful monitoring and told her that surgical intervention was not indicated. Subsequently, she returned to her native country but received poor follow-up and monitoring because of the quality of services and limited access to care.

Given the history of a pancreatic mass with need for monitoring, the primary care provider (PCP) ordered an abdominal computerized scan to confirm the existence of a mass. The scan confirmed the presence of a cystic pancreatic mass without invasion of the adjacent vessels and organs and no evidence of pathologically enlarged lymph nodes in the surrounding areas. The PCP advised the patient to consult with a pancreatic surgical specialist to evaluate the mass, given the recent diagnosis of diabetes, which could be a complication.

The consulting specialist examined the patient, reviewed the abdominal scans, and recommended another radiological imaging technique, endoscopic ultrasound-guided-fine-needle-aspiration to further confirm the type and location of the pancreatic mass. The procedure confirmed the diagnosis as cystadenoma of the body and tail of the pancreas. A cystadenoma is a lesion that contains multiple small or microcyst, which encapsulates a thin and watery fluid that may have a small risk of malignant change (Steer, 2003).

After confirmation of the cystadenoma, the surgeon recommended surgical intervention as the patient's best option. According to the patient, the surgeon's recommendation was based on two premises: (1) to prevent any possible complications in the future and (2) to confirm the diagnosis of the mass as a non-malignant lesion. At the time of this consultation, the patient was in general good health with optimal blood pressure and diabetes control through oral medications and lifestyle modifications. The patient reported that the surgeons reasoning was logical and agreed to the surgery without speaking with the PCP or seeking a second opinion.

Within a month of her initial consultation with the surgeon, she had a distal pancreatectomy. According to the patient, she did not recall discussing the possibility of deterioration of her diabetes and resultant treatment with insulin preoperatively. She also did not recall seeing this complication listed on the written informed consent form.

The only risks she recalled discussing verbally and in writing were infection, bleeding, severe wound pain, obstructed bowel, and pancreatic duct dysfunction. She remembered discussing her convalescent period. She also recalled sharing her concern of being sick when she returned to her native country in one year. According to the patient, the surgeon reassured her that most postoperative complications were usually short-lived and treatable, and she would return to her normal routine within a couple of months. Furthermore, she recalled during her discussion with the surgeon, expressing concern about complete resection of her pancreas and the related complications. The surgeon stated that since the mass was located in the distal portion of her pancreas, her pancreatic function should not be affected.

The intra-operative course was uneventful. The pathology report confirmed a diagnosis of a serous microcystic adenoma and chronic pancreatitis with atrophy and fibrosis. There were no malignant cells in the mass or in the adjacent areas.

Two weeks after the surgery, during a regularly scheduled appointment with her PCP for diabetes and hypertension follow-up, the patient presented with multiple complaints. At the appointment, she informed the PCP of her recent surgery and a resultant significant weight loss. Her blood glucose level was dangerously elevated, and her overall health had deteriorated significantly. She reported fatigue, polyuria, polydipsia, and overall general malaise; although, she had maintained her regular oral hypoglycemic medications and followed a nutritious diabetic diet. Her diabetes was no longer responding to the oral hypoglycemic medications as it did prior to surgery. An evaluation for the presence of a post-operative infection and electrolyte imbalance was negative. Her tentative diagnosis was a postoperative complication that resulted in an exacerbation of her diabetes.

The surgeon was informed, and he agreed to evaluate her the next day. An abdominal computerized scan revealed a pancreatic duct leak from a pseudocyst: a possible complication of the pancreatectomy. Subsequently, the patient underwent a pancreatic duct sphincter rotomy with temporary stent placement to redirect the drainage. Two weeks later, a follow-up abdominal computerized scan revealed no additional leakage or other complications. One week later, the patient was discharged from the surgeons care and advised to continue diabetes care with the PCP. Although, her diabetes had remained in poor control since the discovery of the pancreatic duct leak from the pseudocyst, she was assured that her persistent complaints of hyperglycemia were unrelated to the surgery and that she would not require further surgical intervention or follow-up. She was further assured that the decision to have surgery was the best decision for her condition and that her symptoms would improve over time.

The patient maintained medical follow-up with her PCP. During this time, her blood glucose remained elevated despite oral hypoglycemic medication, adherence to a strict diabetic diet, and regular exercise. She was referred to an endocrinologist, who determined that her pancreas was functioning at a minimal level. She was advised to

start insulin therapy to stabilize her glucose level and prevent any diabetic complications in the future. According to the endocrinologist, failure of the remaining pancreas was most probably an outcome of her surgery. Freedman (2004) concurs that patients who have undergone pancreatectomy may develop exocrine and endocrine dysfunction and the resulting diabetes can be severe and associated with considerable morbidity. The patient stated that she had never been informed of such a possibility prior to agreeing to the surgery.

Given the above-described complication, the patient was discouraged and dismayed. Prior to surgery, her diabetes was very well controlled with oral medication, diet therapy, and lifestyle modifications. Now, her glucose had become impossible to control on the same medications and routine. She concluded that the precipitous deterioration of her glucose level, given no evidence of infection, was most likely related to a permanent complication of the partial distal pancreatectomy. A procedure that she now believed was unnecessary. She resigns herself to the belief that, if she had been informed, she would have never consented to an intervention that carried such potentially devastating consequences. An even more foreboding thought is that she wonders whether the surgery recommendation was driven by financial incentives. She lamented over not having exercised her right to a second opinion because she was unaware of that process; therefore, acquiescing to a convincing suggestion of a health care provider. As such, she became extremely depressed and unmotivated and required care from a psychiatrist.

Discussion of Ethical Principles

This case exemplifies the detrimental and unintended consequences of ineffective communication between a patient and a physician. The surgeon and the patient did not concur on the ultimate goals of treatment. The final outcome invites one to ask the following questions:

1. What were the factors that convinced the patient that surgical intervention was in her best interest?
2. Was she fully apprised of all of the complications and implications of her surgery?
3. What responsibilities do health care providers have to ascertain that patients really understand consent documents?
4. What was the perspective of the surgeon? Did he fully disclose, or was there an attempt to use persuasion in forcing choice?
5. Did the surgeon know and understand the impact of the patients health needs in her native country?

6. What role does one's culture have on one's interaction with health care providers?
7. And, should culture be considered in obtaining consent for services?
8. What was the role of the primary care provider?
9. What responsibility should the patient have taken in her own health care?

There is an expectation from patients that their health care providers always exercise the Hippocratic Oath when caring for them. This is a well-recognized and understood philosophy. It is one of the highest aspirations of duties that physicians have toward their patients. (Mappes and DeGrazia, 2001) When patients choose health care providers to manage their illness or condition, they unequivocally expect that their best interests will be at the forefront. There is also the presumption that the health care providers ultimate goal is to do good with minimal risk of harm. In other words, the health care provider is expected to adhere to the concept of beneficence, which requires that relevant positive efforts be made to secure the well-being of the patient (do good, beneficence) and protect them from harm (do no harm, non-maleficence) (Bulger, Heitman, Reiser, 2002).

In this case, the patient was aware of her benign pancreatic mass for years and remained without any symptoms. When this surgeon advised her to have the mass surgically removed, she believed that this advice would provide her the best outcome. The patient never questioned this advice, although it was different from previous physicians. She believed that she had been fully apprised of her risk and complications when she consented to surgery. Furthermore, she indicated that she trusted that she was consenting to the most current treatment option available in a country with the most advanced medical care.

In many cases, health care providers could face a conflict between doing well and respecting their patient's autonomy. In this instance, the patient entered the medical encounter with the presumption that her autonomy would be respected. She believed the concept of self-determination, which is her capacity to form, revise, and pursue her personal plans of life, would be preserved. (Mappes and DeGrazia, 2001) She presumed that she would be fully apprised of all aspects of her condition, treatment options, and their implications. She was well aware of her short tenure in the United States and would have carefully reviewed any advice that could have impacted on her personal life plans and circumstances. More specifically, she would have exercised much more caution about advice that would impact on her ability to care for her young children especially since she expected to return to her native country within one year. Medical care for insulin-requiring diabetes would be difficult to obtain in her native country. She had discussed this concern with the surgeon. Her right to receive a balanced view of the different treatment interventions was not met.

In this circumstance, it appeared the two values that inspired the ethical foundation of informed consent are in question. (Mappes and DeGrazia, 2001) The patient believed that she was not given unbiased and complete information. She felt that she was led to believe there was a sense of urgency in making a decision. She did not exercise her right to a second opinion or obtain the benefit of a discussion with her PCP for many reasons. First, the patient followed the doctor's advice because she was not familiar with the concept of shared decision making. She presumed the doctor knew best. Secondly, she was unaware of the process of obtaining a second opinion and did not consider it. Thirdly, she perceived her surgeon to be more knowledgeable about her pancreatic mass than her PCP and felt that her PCPs contribution would be minimal. She later realized that her flawed assumptions influenced her decision to forgo researching other important treatment options, including no intervention and continuing to monitor her disease. Finally, she believed that the information she was given to consent to surgery was unbalanced and inadequate for her to have chosen the best treatment option for her life goals.

The physician-patient relationship is another example where the patient's autonomy was not applied. As was noted, autonomy for the sick patient cannot exist outside of a good and properly functioning doctor-patient relationship (Powell, 1995). The surgeon, unfortunately, did not choose to approach his physician-patient relationship as a partnership or mutual pursuit of shared value of health. Otherwise, he would have discovered the patients critical cultural issues regarding diabetes, living with a chronic disease in a foreign country, and the social isolation associated with certain diseases that require daily injections.

A physician's acknowledgement and understanding of a patient's culture is paramount when discussing the various treatment modalities. The awareness of patient's cultural differences could help identify underlying problems as well as provides information about beliefs, values, and preferences (Ells and Cananio, 2002). The surgeon should have been well informed of the patients: (1) fear of the inevitable outcome of possibly losing her sight and limbs due to diabetic complications, (2) concern of being a financial burden to her family given their inadequate resources to care for her in her native country, (3) reality of poor access to quality medical care and supplies in her impoverished native country, and (4) shame and guilt for making a decision that would permanently impinge on her ability to care for her children. Awareness of these issues might have apprised the surgeon of the potential devastating impact on the patient's quality of life. His recommendation might have been modified in light of the likely outcome. His recommendation might have changed to a watch and wait approach or no surgical intervention with careful regular monitoring as she had been previously advised.

Conclusion

The standard of care for symptomatic or enlarging serous cystadenoma is to perform a partial pancreatectomy. (Steer, 2003) Once the diagnosis is confirmed, the

management options are determined by patient symptoms, progression of lesion, and lesion location. (Steer, 2003) It is apparent that the surgeon believed that she met one or more of the criteria for a surgical intervention. This is consistent with his rationale that surgery was her best treatment option. The surgeon's decision to advise the patient to have surgery met the standard of care for managing a cystadenoma; however, it is debatable whether he considered all the implications of surgery for this particular patient. Additionally, it is not clear that he reviewed all the possible surgical complications with her. Although the complications were outlined in the consent form, she reported the complication of an ineffective pancreas was not emphasized during their discussion. She suggested that she was dissuaded from focusing on this complication because she was told that it was unlikely based on the location of the mass. The patient did not thoroughly review the consent form and decided to have the surgery without the benefit of full comprehension or an advocate to clarify the potential complications. Based on the outcome, she believes that the distal pancreatectomy was not in her best interest.

Although, it is impossible to alter this patient's outcome, there are lessons that can be learned from this scenario. First, it is imperative that PCPs educate patients when initiating referrals. Patients need to be educated on the referral process, the right and process of obtaining a second opinion, the prerogative to have an advocate that is either a health professional, family member, or friend, and the right to a complete review of the consent form with a translator, if needed.

Second, physicians and other health care providers need to be cognizant of the needs of the patient to avoid future misunderstandings. They need to be aware of the potential for unexpected outcomes and legal liability consequences that could result from lack of complete transparency of medical and surgical interventions. Health care providers need to understand the significance of patient's personal circumstances, including cultural differences, health goals, and accept that the patient's goals may be incongruent with theirs. Health care providers should involve other health professionals in the decision-making process to ensure the patients best interest remains the primary basis for the chosen plan of care

Third, much has been written about the models of relationships in health care. The paternalistic model presumes the locus of decision-making is the health care provider and the relationship is asymmetrical and hierarchical. Whereas, the partnership approach presumes a collegial relationship where there is collaboration in the pursuit of shared value of health (Mappes, DeGrazia, 2001). It isn't always clear which relationship patients prefer. At this time, the patient's right to complete information and transparency with their medical care is the standard of good health practice. Patients expect to be approached with open communication, care, respect, and understanding of their health belief model. While this approach could be challenging for many health care providers, patients have become empowered and are demanding their right to full disclosure of their medical condition and the related treatment options.

Finally, as health care providers, we need to educate patients about the patient-friendly resources designed to inform them about their condition and treatment. In other words, patients need to be educated on how to assume some responsibility for their own health care. These health and educational resources provide comprehensive and pertinent information to expand patient knowledge as well as guide in selecting treatment plans.

References

- Bulger, R. E., Heitman, E., Reiser, S. J. (2002). Research with Human Beings. In *The Ethical Dimensions of the Biological and Health Sciences* (2nd Ed.) (pp. 119) Cambridge: Cambridge University Press.
- Ells, C. and Caniano, D. A., (2002). The Impact of Culture on the Patient-Surgeon Relationship. *The Journal of American College Surgeon* 195:4, 521
- Freedman, S. D. (October 25, 2004). Treatment Of Chronic Pancreatitis. Retrieved on April 5, 2005.
- Power, EJ. (1995). Identifying Health Technologies That Work. *The Journal of the American Medical Association* vol. 274, 205.
- Mappes, T. A. & DeGrazia, D. (2001) *The Physician-Patient Relationship*. In Mappes and DeGrazia (5th Ed.), *Biomedical Ethics*. (pp. 56-66) New York: McGraw-Hill.
- Steer, M. L (October 23, 2003). Cystic Lesions of The Pancreas. Up To Date, Retrieved May 4, 2004, from, <http://www.utdol.com/application/topic.asp?file=pancdis/2198&type=A&selectedTitle=12>.