ANALYSIS OF THE 'INFORMED CONSENT' AS A MERGING POINT BETWEEN THE NETWORK OF MEDICAL SCIENTISTS AND THE NETWORK OF LAY PATIENTS

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Abstract

The 'informed consent' is a terminology that denotes the process of providing medical knowledge to the patient and getting his signed consent/agreement. The patient who usually lacks medical knowledge needs to be provided with sufficient information about his condition and the treatment he will go through. This information should include all possible side-effects and other alternate treatment choices he can choose from. And the scientific information is provided by the doctor who is in charge of caring the patient. My view is that, therefore, the informed consent is the point where two different and separate knowledge networks merge into. These two networks are the professional knowledge network of medical scientists and the lay knowledge network of the patient. This paper argues that the importance of 'informed consent' not only lies in the ethical matters, but also in the power structure of these two networks. The second argument of this paper is: the informed consent is extremely important because it is one of the few meeting points of medical science where bi-directional communication between experts and lay public is produced. Other meeting points this paper analyzes are: printed material such as books [uni-directional], mass-media such as TV [quasi-unidirectional], interactive media such as Internet [quasi-bidirectional].

Keywords: informed consent, actor-network theory (ANT), doctor-patient relationship, power/knowledge network

1. Introduction

Mr. Kim has been sick. He went to the hospital and was told by a doctor that he needs an immediate operation to survive. However, the doctor also said that there are alternative cures that can treat Kim's disease. But each methods (including performing an operation) has its own risks and benefits. Now Kim needs to decide which treatment method he will receive. But how? He is not a specialist. The doctor who diagnosed Kim is the expert. The doctor knows way much better about Kim's physical condition and the probable best method for Mr. Kim. Still, we can not give the doctor full control over Mr. Kim's treatment since the one who will be being treated, and the one who is really at the center of this discourse is Mr. Kim, not the doctor. Yet the one with better knowledge is the doctor, not Kim.

This is where the common dilemma of 'informed consent' comes in. In above situation, the case will be usually handled in this way: the doctor will choose a method he thinks is the best for Kim, and Kim will sign a form named 'informed consent' and follows the treatment that doctor had recommended. The informed consent hereby signed by Mr. Kim is a document that denotes enough information about treatment method and possible alternatives had been communicated between the doctor and Mr. Kim. Also it means that Mr. Kim had enough information to decide on his treatment, (therefore the 'informed' part of the 'informed consent') and after considering all possible means he decided to follow the doctor's recommendation (therefore the 'consent' part of the 'informed consent').

2. The History of Informed Consent

This doctrine of informed consent first appeared at English court in 1776 where a surgeon was held liable for using an experimental treatment to a patient with a broken leg. The court ruled against the surgeon for not having properly informed his patient of the fact. [1]

But it was in the middle of 20th century that this doctrine was recognized of its humongous importance. After World War II, Nuremberg War Crimes Trial was held in the city of Nuremberg, Germany between 1945-1949. The Nazi doctors who had committed egregious crimes in the name of 'medical experiment' at concentration camps were charged in the trials. The shocking truth of what had happened in the Nazi camps was revealed. But the doctors had defended themselves that experiment is essential in the development of science, and that's what they had to do during war times. Nuremberg Trial led to the birth of the Nuremberg code. This was a "monumental statement by a court of law concerning the ethical principles that should govern research on human beings." [2] Here, the Nuremberg Code directs that the voluntary consent of the human subject is absolutely essential.

Following it was a Tuskegee revelation. On July 26, 1972 The New York Times published a story. It reads: "For forty years, the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without treatment for the disease…… the study was conducted to

determine from autopsies what the disease does to the human body. …… [the subjects of the study were] about 600 black men, mostly poor and uneducated, from Tuskegee, Alabama." [3] The study began in 1942 and lasted till the publication of the story in NYT. By then, the cure for this venereal disease - the penicillin - was already found. Doctors could easily have cured the patients with it. But they deliberately chose not to, in order to conduct a medical research on human subjects. [4]

It led to a wide discussion and social uproar. In 1974, Congress passed the National Research Act which created National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, who wrote the Ethical Principles and Guidelines for the Protection of Human Subjects of Research, commonly known as the Belmont Report. The Belmont Report was then published in the Federal Register in 1979.

The Belmont Report has three basic principles: respect for persons, beneficence and justice. And the first principle, 'respect for persons' states the informed consent is the essential part of the medical science. It tells us that, "Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. Informed consent is not just a for of a signature, but a process of information exchange that includes subject recruitment materials, verbal instructions, written materials, question/answer sessions and agreement documented by signature. The Belmont Report states that the consent process can be analyzed as containing three components: information, comprehension and voluntariness." [5]

Here we have three important components to form a valid informed consent – (1) information, (2) comprehension, and (3) voluntariness. I would like to change these three factors as following keywords: (1) knowledge, (2) understanding, and (3) autonomy. The reason for this renaming will be discussed at the end of section 3.

3. The Concept of Informed Consent

3.1 Knowledge

Knowledge, which is stated in the Belmont Report as 'information' constitutes the first factor of the informed consent. However as we've seen in Mr. Kim's case in the introduction section of this essay, usual patients are not equipped with proper medical knowledge. Therefore, many courts demand that the 'duty to disclose' on the doctor's side is much needed. It is defined "not by the amount of information that the doctor thinks the patient should know, could handle or might want to know, but by the amount of information that the patient needs so that they are able to make an autonomous choice." [6]

3.2 Understanding

Understanding, which is stated in the Belmont Report as 'comprehension' constitutes the second factor of the informed consent. This is the key factor in the Public Understanding of Science (PUS). A patient, who belongs to public, first needs to receive full knowledge from the expert (a doctor). Then the doctor needs to make his/her best effort to make the patient actually understands what had been said. Same applies for the patient's side. S/he also needs to make best effort to understand the knowledge handed to him that relevant to his/her making choices. Here we can see how PUS works in the small section of informed consent.

3.3 Autonomy

Autonomy, which is stated in the Belmont Report as 'voluntariness' constitutes the third factor of the informed consent. The patient is expected to make his/her own choices under no influences from outside. It is analyzed that X is said to act autonomously only if X acts:

i. intentionally [condition of intentionality],
ii. with understanding [condition of understanding], and
iii. without controlling influences [condition of noncontrol].

Therefore, if a patient who has been well informed with proper medical knowledge understands what s/he will go through and decides that s/he will follow the treatment without doctor's coercion, this is an informed consent. The patient has made an autonomous decision. But in many cases, these are not so clear as they seem to be. Faden and Beauchamp argues that there are many different scopes how autonomy operates. Faden and Beauchamp also showed that there exist 'gray area' or 'borderline area' where it is not so clear if the assent was taken autonomously or coercedly. They introduced following two diagrams to show how the continuum of influences exists on the spectrum. [7]

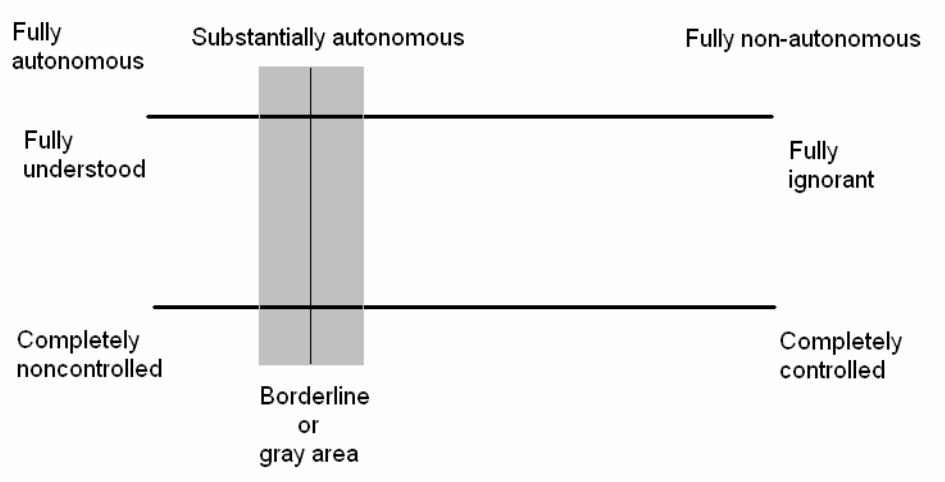

Figure 1. Degrees of autonomy (Faden and Beauchamp, 1986)

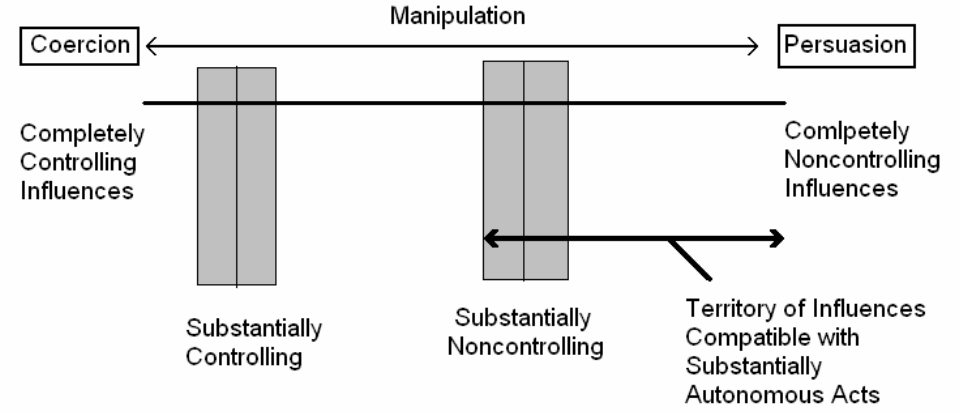

Figure 2. The continuum of influences from controlling to noncontrolling (Faden and Beauchamp, 1986)

Fig. 1 and Fig. 2 explain how the spectrum of autonomy works in medical sciences. When a medical doctor gives information to the patient, the patient needs to recognize the relevant problems and situation well enough to make his/her autonomous decision. As the graph on Fig. 1 shows, if the patient is not fully aware of the situation, it cannot be said that s/he made an autonomous decision even if there was no outside influence. Fig. 2 intensifies this narrative and explains that if there was not enough understanding from the patient when a certain decision was made, it is same as the decision was made by coercion. We understand this narrative by considering how the patients were treated in the Tuskegee syphilis experiment. In Tuskegee experiment, patients were uneducated low-income class of African-American males. And they were treated without any knowledge of their disease, nor what treatment they could receive instead. So the case must be considered as being consisted of non-autonomous consents from patients which were made under coerced and controlled manipulation.

4. Two Networks of Power/Knowledge

4.1 The Knowledge Networks

All these considered, we can draw a sketch of what 'informed consent' truly means to patients and doctors. Informed consent consists of three factors to be legitimate: knowledge provided to the patient, knowledge understood by the patient, and patient's autonomous decision based on the provided-and-understood knowledge. Knowledge is the key factor. If the doctor had not provided the patient with enough knowledge, or if the knowledge handed to the patient was not properly comprehended, then it can't be said that proper informed consent was made.

Medical doctors who give information to their patient are equipped with expertise in medical sciences. Medical knowledge is the key resource of their occupation and expertise. On the other hand, however, the patient is usually lay person who lacks expertise in medical knowledge. Therefore what the patient intends to do in the informed consent process, is to use the best available resources of medical knowledge s/he could use of at the time of making the decision. This includes not only the medical knowledge provided by the patient's doctors, but also includes books, mass media such as TV programs, newspapers and magazines, science journals, information on the web, and other people's

experience. If the patient has someone close to him/her who works in the medicine/health-related sector, e.g. a relative who is a surgeon, a friend who works as an editor in medical journals, or a neighbor who had suffered similar illness, the patient will actively look for their knowledge to help himself/herself make a better decision. If the patient suffers from a terminal illness or a disease that is hard to cure, the patient's family members and friends will also actively participate in the process of acquiring knowledge that might help their beloved one to overcome the illness.

These behaviors and practices form a network; and this network is made up of knowledge. The knowledge network is composed of many heterogeneous objects. It includes professional knowledge they obtained from mass-media, passage from a book, conversation with a surgeon-relative or a science journal editor-friend. Information from the doctor in charge of the patient during the informed consent process is also included in the patient's knowledge network. As a matter of fact, the information doctors give their patient during obtaining the informed consent process, is to empower their patient with enough knowledge to help them make rational decision. [8] A person without proper knowledge cannot make a reasonable decision. That is, a person who is equipped with the knowledge network that is not powerful enough to guide him/her in the informed consent process, cannot be said to have made an autonomous and logical decision.

We can draw this situation as the following diagram.

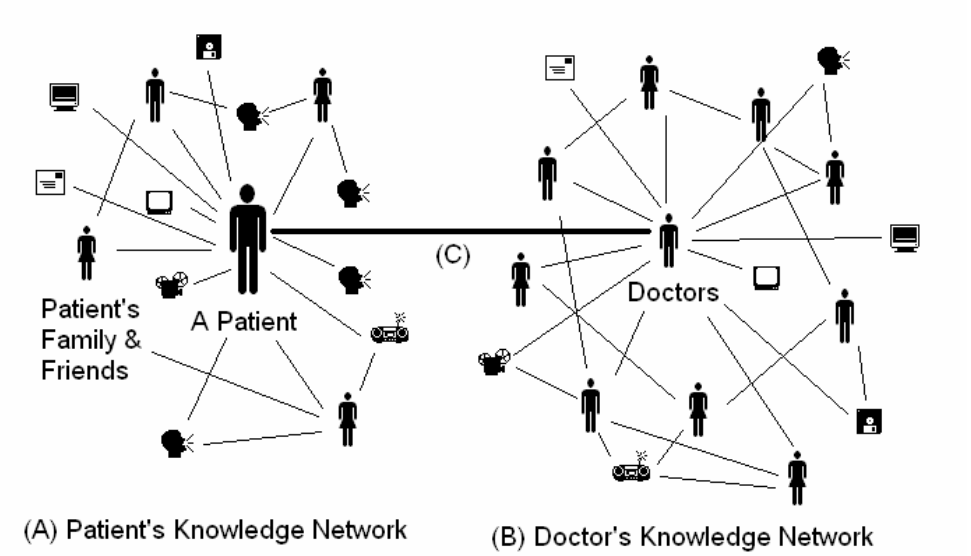

Figure 3. Two knowledge networks: one of the patient's and one of the doctor's

Fig. 3 shows two knowledge networks. Each icon in the picture shows a source of knowledge. The distance between the icon and the person shows how much impact the source has on the person.

Network (A) is the patient's knowledge network. The patient's network is composed of many heterogeneous sources: his family, friends, knowledge from radio/TV, information from books, information from Internet, and so on. Some of them are professional (such as the one from books) and some of them are amateurish (such as the conversation with person around him/her). Some information is dubious (such as the one from Internet or from pseudo-medical TV programs such as E.R. or C.S.I.). Some information is not directly obtained by the patient; they are heard by another people in the patient's circle and then handed over to him/her by them. One thing to notice in the patient's network is that knowledge from the mass media is located very near the patient, which means they exert great power on him/her.

Network (B) is the doctors' knowledge network. Their network is equipped with more expertise since there are a lot of other medical doctors and professional journals included in their network. Also, in the expertise knowledge network of doctors, actors such as TV programs and conversation with non-medical scientists play very little roles. (In the diagram, they are located rather outside of the network.)

Then, what does the line between these two networks, which is denoted as (C) in the diagram do?

4.2 Informed Consent as a Merging Point between the Network of a Lay Patient and the Network of Medical Scientists

(C) is the connection between the patient and his/her doctors. (C) is where the patient and the doctors exchange conversation. The doctors try to explain the patient's condition to him/her and give him/her possible choices of treatment. The patient hears from the doctors about his/her medical condition, and if s/he has questions s/he can ask the doctors and gets the answer until s/he gets full knowledge and understanding about his/her situation. Also the doctor can hear about the patient's amateurish remarks on his/her opinion, and can correct it if needed.

(C) is where the patient's knowledge network is connected with the doctor's knowledge network. In other words, (C) is where the patient's network and the doctors' network meet together. The two networks merge at point (C). This is

the characteristics of what happens in the process of obtaining an informed consent from the patient. Therefore (C) is the point of the 'informed consent'.

Two knowledge networks sometimes clash at (C). For example, when the patient has a terminal cancer, s/he might refuse to go into painful procedure of getting a radiation treatment. S/he might want to instead go on alternative medicines. S/he might even want to turn to the religious healings instead of giving full control of his/her treatment to the doctors.

Above diagram and the analysis of viewing the informed consent process as the point where two different networks merge also helps to understand why the properly informed autonomy is regarded as the most important factor in many ethics-related medical declarations such as the Belmont Report and the Declaration of Helsinki. In most cases, the patient is a lay person lacking professional knowledge of his/her condition, while the doctors have firm and huge networks of expert knowledge behind them. The fulcrum of the leverage is on the doctors' side. Then, what insight can we obtain from this fact?

4.3 The Fulcrum of the Leverage between Two Power/Knowledge Network

Michelle Foucault has shown that how knowledge and power act as a whole, just like two sides of one coin. [9] We can import the Foucauldian concept of power/knowledge in the discourse. It is plausible since medical experiments and surveys are filled with discourses of power. (For example, many feminist ethicists argue that the autonomy in the informed consent process it the opposite of paternalism which is phallic and exerts forceful power on the subject. [10] [11]) Then we can rename the knowledge network of patient's and the knowledge network of doctors' as the power/knowledge network of patient's and the power/knowledge network of doctors'. In following step, let us compare these two power/knowledge networks. Please refer to Fig. 4.

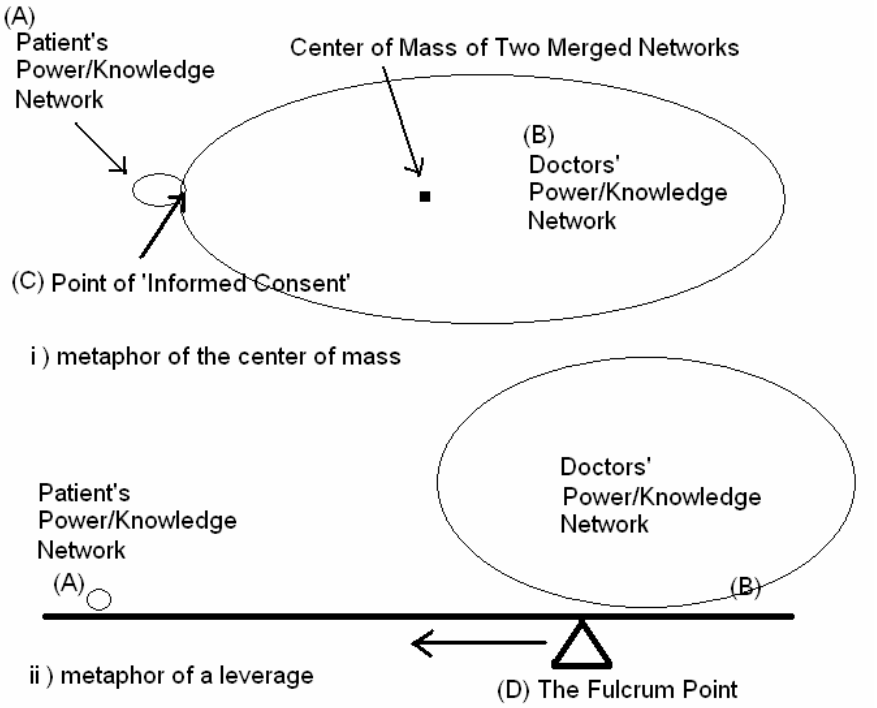

Figure 4. Comparison of two power/knowledge networks

In Fig. 4, the patient's power/knowledge network and the doctors' power/knowledge network are compared. Seen in the upper picture of Fig. 4 is the metaphor of the center of mass. Without doubt, the network of medical scientists that is equipped with lots of expertise and professional knowledge, is much larger and powerful than the small network of the patient. If we merge these two networks at the point (C) of 'informed consent' as we've seen in Fig. 3, the center of mass is usually located on the doctors' side. If we use this comparison metaphor and project it on a leverage (as seen in the lower picture of Fig. 4), the fulcrum point is located near the doctor's power/knowledge network. This means that medical scientists have more power/knowledge than the lay patient.

The demand of informed consent in ethical guidelines is the effort to even out this unbalance. It is same as the effort to move the fulcrum point of power/knowledge (shown as (D) in Fig. 4) to the center (shown as the arrow). Lay patient cannot have the same amount of expertise and knowledge as the medical doctors, but at least regarding the situation the patient is in, it is an ethically worthwhile and mandatory trying to provide the patient with as much relevant information as possible. Through this effort can the patient achieve substantial autonomy, according to three conditions of an informed consent.

5. Various Aspects of Knowledge Resources

Before ending this essay, let me argue one more important aspect of an informed consent. As delineated in Fig. 3, the patient obtains his/her knowledge from various and heterogeneous resources. These include printed materials such as books, and mass media such as TV/radios. Newly introduced resources include interactive media such as the Internet.

In printed materials, people acquire knowledge unidirectionally. Information is given to the readers. There exists no feed-back routine; all the reader can do is to decide whether to read the book or not to read the book. The reader can also choose different books as another source of information. But the unidirectional manner in which information is given persists. Some TV programs that are designed to give medical information to the watchers also belong to this category.

In mass media such as radio programs and newspaper, information is communicated quasi-unidirectionally. Unlike printed materials where there is no feedback, some radio/TV programs now have Q&A section where listeners/watchers can call in and ask the panels. Medical experts on the show then answers instantaneously to the questions the caller had asked. But these are not completely liberal structure. There are time limits, and sometimes the calls are pre-monitored. Some newspapers and magazines have similar Q&A sections where the readers can send in their questions by mail or FAX, and the experts answer them on the published paper. Although this is not a perfectly unidirectional form of information giving, there also exist many limits such as space on the paper, and the questions are filtered by editors. Therefore, these modes of knowledge acquisition can be said to be quasi-unidirectional.

Next form of knowledge resource is an interactive media. Most recently entered in the scene is the Internet where people can post their questions, experts give them tailor-made knowledge that fit the patients' situation perfectly. This form of knowledge exchange is done on personal blogs run by doctors, hospital web pages for the purpose of patient support and advertising effects, or on support group websites run by people who suffer same diseases. They actively intercommunicate and exchange knowledge. Therefore this mode of knowledge resource can be analyzed as working bidirectional. However since they are only maintained in the cyberspace, problem of digital divide can work against people of specific socio-economical classes. Problem of accessibility and many technical problems such as lockdown of the server, truncation of the literature to fit the allotted text space, or attacks of the hackers can be obstacles in free knowledge exchange. It would be reasonable to classify these as quasi-bidirectional mode of communication.

Let's consider then what happens in the informed consent procedure. A patient (sometimes along with his/her family members) and a doctor (sometimes doctors) sit together vis-à-vis. Unlike other modes of communication mentioned above, while making an informed consent, key actors – the patient and the doctors – share same time and space. They exchange information freely almost without any limitation. First, full knowledge is given by the doctors to the patient. Then in order to properly comprehend physical/mental condition s/he is in, the patient and other people who consists patient's knowledge network such as family members/friends ask whatever they want to know. And the doctors give their expert knowledge on the site. There exists full feedback routine; this is bidirectional communication.

There are four modes of communication: unidirectional, quasi-unidirectional, quasi-bidirectional and bidirectional. Among many possible ways a lay patient can communicate with medical doctors, in the process of informed consent we see perfectly bidirectional information exchange between two groups of people. A process of informed consent is one of the few meeting points of medical science where bidirectional communication between experts and lay public(patient) is produced.

6. Conclusion/Summery

The doctrine of informed consent is the effort to provide equality and rights to the lay public. Still it has been suspected by many ethicists that the practice of informed consent "may have created a façade of patient involvement and control, when, in fact, the power still remains with the medical decision-maker." [12] And scholars engaged in the discourse try to seek justice beyond simple rule of getting an informed consent. [13] However while not perfectly satisfactory, informed consent is the best available tool we have so far to ensure the patients' rights and give them autonomy as well as power to make decisions. The informed consent is the point where patients' power/knowledge network and the medical scientists' power/knowledge network meet. And it is one of the few places where substantially bidirectional communication of knowledge between medical experts and lay public take place. This analysis renders more importance to the doctrine of informed consent.

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