Deep brain stimulation: At your own risk

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***Abstract*—Deep Brain Stimulation (DBS) surgeries are not new, although they were only granted approval in the U.S. by the U.S. Food and Drug Administration (FDA) in 2002 for advanced Parkinson's Disease (PD). In 2016, DBS surgery was approved for earlier stages of PD. This does not mean that DBS surgery, generally considered minimally invasive, does not come without commensurate risks. The Mayo Clinic identifies DBS as a serious and potential risky procedure, whereby those eligible must carefully weigh pros and cons. The aim of this paper is to provide a general overview of deep brain stimulation surgery and to present the findings of available informational resources on 14 hospital and medical center web sites that were reviewed, pertaining to surgical procedures and policies: pre-operative to post-operative. The article focuses on critiquing available educational DBS materials and their adequacy in addressing potential risks of DBS surgery. The findings indicate that hospital informational resources on the DBS surgical technique reaffirm each other's educational materials and that they positively inform patient decision-making. These factors can be linked to better post-operative recovery. However, the materials provided by the hospitals overemphasize the positive aspects of DBS with relatively little detail about potential side effects. This article also outlines the potential short-term and long-term side effects of DBS surgery as identified by the DBS educational literature found on the hospital web sites reviewed.**

Keywords—DBS, deep brain stimulation, risk, patient information, hospitals, policies, procedures, education, pre-operative, post-operative, web sites, videos

I. Introduction

Body modifications are increasingly prevalent in our society [1]. It is important to understand what they are and their potential implications on health [2]. Implants are a complex body modification that can feature a technological component [3]. These can be divided into three categories: practical/convenient [4], cosmetic/aesthetic [5] [6], and medical implants [7]. Medical implants are placed inside or on the surface of the body for the purpose of correcting a medical condition [8]. This article will examine policies and procedures related to deep brain stimulation [9], which falls under the medical implant category. Deep brain stimulation (DBS) is a medical procedure in which electrodes are implanted into the brain to produce electrical stimulation in regions of the brain that produce movement [10]. This procedure is most commonly used to treat movement disorders such as Parkinson's disease, essential tremor, and dystonia [11]. It has also been used to treat psychological conditions such as obsessive-compulsive disorder (OCD) and depression [12].

A. Aim

The aim of this article is to examine the literature found on hospital and medical center web sites, pertaining to the DBS surgical technique, used to inform the public, in particular future patients of DBS that may be living with movement disorders, and other mental health conditions and considering a variety of options to address their health circumstances. With the growing number of DBS operations in the USA, "experimental technique" labels are now redundant as DBS is considered only a "minimally invasive" technique [13], though the safety risks are still presented to patients. It is left to the individuals living with a condition weigh the risks and benefits of the treatment before embarking on the procedure. Therefore it is important to evaluate the quality of information that is provided on a hospital's website since 33% of potential patients receive their information about DBS from the Internet [14]. It is also critical to examine the quality of information that the hospital provides as 43% of potential DBS candidates simply agree to undergo the procedure when their physician recommends it to them, with little knowledge about the procedure [15]. Some patients display reluctance to undergo the procedure out of fear of complications [16].

The paper is divided into five sections: section II provides a brief literature review, section III describes the methodology undertaken, followed by section IV presenting the results, section V contains the discussion, and section VI ends with a conclusion and prospects for future research.

II. Literature Review

Deep brain stimulation is defined as an elective surgical procedure in which electrodes are implanted into certain areas of the brain to generate impulses that control abnormal brain activity [17]. DBS has become a routine procedure for treating Parkinson's disease [18] and is also used to treat other diseases such as essential tremor, dystonia, and Tourette syndrome [19]. Parkinson's disease is a progressive neurological disorder that affects motor control often resulting in tremors, stiffness, or slowing of movement [20]. Essential tremor is also a neurological disorder that results in involuntary and rhythmic shaking [21]. Dystonia is a movement disorder in which the muscles contract involuntarily, causing repetitive or twisting movements [21]. Tourette syndrome is a disorder characterized by repetitive movements or unwanted sounds that cannot be easily controlled [22]. These disorders all involve issues with motor control, making these patients good candidates for receiving DBS. DBS has also been used to treat psychiatric disorders such as obsessive compulsive disorder (OCD), major depressive disorder (MDD), addiction, anorexia nervosa,

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anxiety disorders, autism, and schizophrenia [23]. DBS is still considered to be an experimental therapy for treating psychiatric conditions, especially mood disorders [24].

A. How does DBS work?

DBS works by targeting specific regions within the basal ganglia to correct abnormal activity [18][25]. The basal ganglia is responsible for motor control, motor learning, executive functions and behaviors, and emotions [26]. Specific structures within the basal ganglia that are targeted include the subthalamic nucleus, globulus pallidus interna, and the thalamus [27]. Once the desired regions of the brain are targeted, electrodes are implanted and stimulation is applied [28]. Different levels of stimulation are applied based on the location of the electrodes and the severity of the disease. The device consists of three distinct components:

- the electrode (Fig. 1)
- extension wire, and
- internal pulse generator (Fig. 2).

The electrode is implanted into the desired area of the brain. Then the extension wire is passed under the skin of the head, neck, and shoulder, and the extension wire connects to the internal pulse generator. The internal pulse generator is implanted underneath the skin of the chest [17].

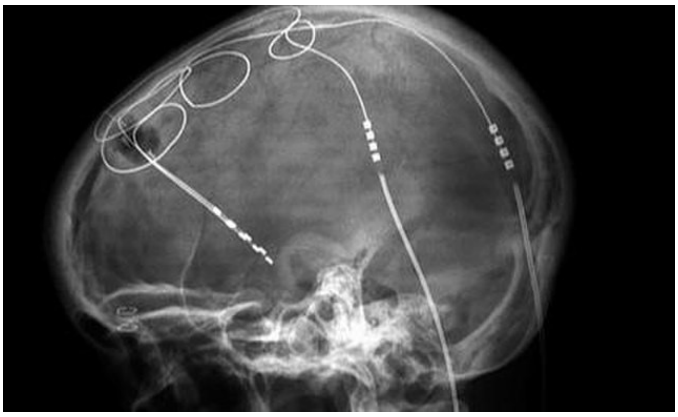

Figure 1. Deep Brain Stimulation Probes of the Skull by Dr. Craig Hacking and A. Prof Frank Gaillard CC-SA 4.0 [29]

As with any surgical procedure, DBS poses some risk for patients. Merriam-Webster defines risk as the "possibility of loss or injury," "someone or something that creates or suggests a hazard," or "to expose to harm or danger" [31]. Risks from DBS can come as a result of surgery, hardware failure, stimulation, and medication changes [17][18]. However, the risk of experiencing serious or persistent complications should be less than 2% in a hospital or medical center with a quality DBS program [28]. The incidence of experiencing any serious complications are especially low in psychiatric patients [32].

B. Decision Making for DBS

There are various reasons that may lead to a patient's decision to receive DBS. Some patients may take their own initiative to receive DBS, while others simply agree to the procedure when it is recommended by their physician [15]. Patients choose to receive DBS because the benefits of the procedure are perceived to greatly outweigh the potential side effects. Potential candidates are more willing to receive DBS if the symptoms of their disease are more severe [33]. Candidates also have to consider the balance between the relief of symptoms and the side-effects that are induced by the device [15].

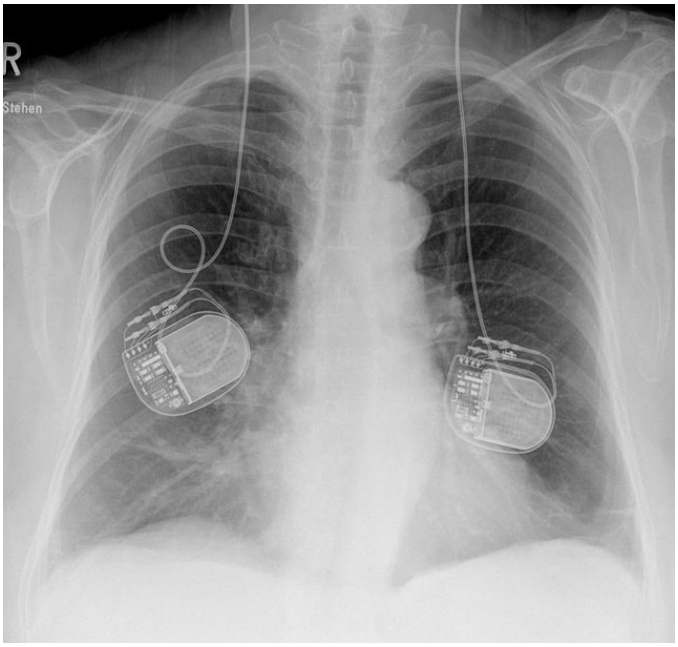

Figure 2. DBS Pulse Generators by Hellerhoff CC-SA 3.0 [30].

III. METHODOLOGY

The aim of this qualitative study was to explore the policies and procedures of deep brain stimulation, in 14 different US-based hospitals and medical centers that offer the DBS surgical technique (Table 1). Hospitals and medical centers were selected based on policy information that was publicly available through searches conducted in March 2019. The website of each hospital/medical center was examined to find information regarding their deep brain stimulation policies and procedures. This was done by performing a systematic search using the following keywords in various arrangements: "DBS" or "Deep Brain Stimulation" AND "types" OR "risks" OR "procedures" OR "side effects." Information collected from these sites was compared and contrasted to look for common trends and also similarities and differences in policies and procedures. While dozens of hospitals now perform the DBS procedure, across the USA, literal replication (where case data pointed to similar results in procedures/policies) was reached in the seventh examined hospital.

TABLE I. LIST OF HOSPITAL WEB PAGES REVIEWED THAT CONDUCT THE DBS SURGICAL TECHNIQUE

Date Access	DBS Surgical Technique Hospital Web Sites
	Hospital Name - URL
09/20	University of Minnesota - https://udall.umn.edu/files/deep-brain-stimulation-dbs-parkinsons-disease
09/20	Barrow Neurological - https://www.barrowneuro.org/specialty/deep-brain-stimulation-dbs/
10/20	Colorado Children's Hospital - http://www.childrenshospital.org/conditions-and-treatments/treatments/deep-brain-stimulation/in-depth
10/20	Dignity Health - https://www.dignityhealth.org/arizona/locations/stjosephs/services/neurology-neurosurgery/muhammad-ali-parkinson-center/deep-brain-stimulation
10/20	Johns Hopkins - https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/deep-brain-stimulation
10/20	Mayo Clinic - https://www.mayoclinic.org/tests-procedures/deep-brain-stimulation/about/pac-20384562
10/20	University of Wisconsin - https://www.uwhealth.org/neurosurgery/deep-brain-stimulation-dbs/12762
11/20	Northwestern Medicine - https://www.nm.org/conditions-and-care-areas/treatments/deep-brain-stimulation-dbs
11/20	NYU Winthrop - https://nyuwinthrop.org/services/neuroscience/neurosurgery/areas-of-expertise/deep-brain-stimulation/
11/20	Oregon Providence - https://oregon.providence.org/our-services/d/deep-brain-stimulation/
11/20	Rush University - https://www.rush.edu/treatments/deep-brain-stimulation
11/20	St. Luke's - https://www.saintlukeskc.org/condition/deep-brain-stimulation
11/20	University of California, San Francisco - https://www.ucsfhealth.org/treatments/deep-brain-stimulation
11/20	University of Iowa Hospitals and Clinics - https://uihc.org/deep-brain-stimulation-dbs

A. Internet-Based Qualitative Data

The information systems methodology to analyze Internet-based qualitative data was used and adapted to analyze information from hospital resources [34]. This methodology consisted of three steps: elicitation, reduction, and visualization. Information was gathered from within each hospital website using the search function. The following keywords were used to find information regarding DBS in each hospital website: deep brain stimulation, types of deep brain stimulation, what to expect from deep brain stimulation procedures, risks, side effects, and after care. Informational DBS webpages were thoroughly searched for information regarding the device, procedure, potential risks and side effects, and aftercare. Links within DBS webpages were followed to find more in-depth information. Information was collected from informational articles and videos. Information from each hospital was collected and organized in a spreadsheet under the following category headers:

- Eligible candidate for DBS
- Procedural expectations
- Surgical risks
- Side effects of the surgery; and
- After the surgery.

Data from these categories were then used to find similarities and differences between hospital policies.

IV. RESULTS

A. General Educational DBS Application Resources

Upon performing a comparison between the 14 hospital websites, it was found that nearly all of them provided a detailed explanation of who is eligible for DBS, the surgical procedure, the risks associated with the surgery, how to perform appropriate aftercare, as well as the long-term effects of the surgery.

Many of the hospitals and medical centers defined people who have been diagnosed with Parkinson's disease, essential tremor, dystonia, Tourette syndrome, and epilepsy as ideal candidates for undergoing the DBS procedure [12][35]–[41]. Specifically, the medical centers websites indicated that people with the above listed conditions should receive DBS if their condition is affecting their ability to perform daily activities and/or if they experience fluctuations with their mobility, despite taking medication.

B. Informational Videos about DBS Surgery for Patients

It was found that the hospitals and medical centers included information to educate their patients about how the surgical procedure works as well as the aftercare protocols. Many of the webpages included informational videos to help their patients understand what the surgery will look like while it is taking place. This was advantageous in two ways: first to ensure that patients received some educational information prior to meeting with a neurosurgeon to raise their awareness of the procedure, and second to ensure uniformity in the messaging and communication with respect to those choosing to undergo the DBS surgical technique. In the videos it was explained that the surgery occurs in three stages: electrode placement, generator placement, and device activation. These stages are outlined in Table 2. The electrode placement is generally performed when the patient is awake to ensure proper motor function. A week or two after the electrode placement surgery, the patient will undergo generator placement surgery. In this surgery, the generator is implanted into the patient's chest while the patient is under anesthesia. Two weeks after this generator surgery, the device will be activated [12][37][38][42]–[44]. Providing this information in the public domain is important for educating patients who are considering the surgery. Although no assessment was made on the quality of the information, each video corroborated the other's presentation.

TABLE II. DEEP BRAIN STIMULATION PROCEDURE STAGES

Stage	DBS Procedure	
	Deep Brain Stimulation Surgical Procedure	***Description***
1	Electrode Placement	- Performed when patient is awake - Patient receives local anesthesia - Patient's head is secured in a frame - Surgeon makes incisions for the electrode
2	Generator Placement	- Performed when patient is awake - Generator will be placed in the chest - Incision behind ear is reopened - Wire from ear is connected to the generator - Procedure takes 2-3 hours
3	Device Activation	- Performed 2 weeks after generator placement - May take several appointments to get settings correct

C. Informational Resources for DBS Patient Aftercare

The hospital websites also provided vital information for potential patients regarding aftercare protocols. In many of the websites, a separate section was dedicated to explaining how to ensure an optimal recovery. This information was divided into (1) what happens in the hospital, and (2) what happens at home. In the hospital, the medical staff will monitor the patient for any complications, such as seizures, that may occur after the surgery. The staff will also inform the patient of how to care for themselves at home. After patients leave the hospital, it is recommended that they monitor their incision sites for any drainage. The patient must also use care when showering by using a gentle shampoo and later they should gently pat the incision area to dry it [12][13][37]–[39][42][44]. Providing this information prior to the procedure is important for making patients aware of what the expectations of them will be, before they consent to the surgery.

D. Potential Risks of Deep Brain Stimulation Surgery

The hospital websites also explained the potential risks of deep brain stimulation. Since this a surgical procedure in which a foreign device is introduced into the body, there are many associated risks. These risks include infection, the electrodes moving within the body, leaking of cerebrospinal fluid, stroke, difficulty concentrating, seizure, and headache. Cerebrospinal fluid is a clear fluid that surrounds the brain and spinal cord and functions to prevent injury, deliver nutrients, and remove waste from the brain. A leak of cerebrospinal fluid can occur when there is a tear in the outermost layer of connective tissue surrounding the brain and spinal cord [45]. A seizure is defined as a sudden, uncontrolled electrical disturbance in the brain [46].

Additional severe risks associated with the brain surgery are meningitis; changes in personality, memory, thinking, or language skills; tingling in face, arms, or legs; weakness, balance changes or new involuntary movements; and slurred speech, soft voice or other problems talking or swallowing. Meningitis is defined as an inflammation of the protective membranes surrounding the brain and spinal cord [47]. There is also the potential for the device to stop working over time [12][13][38][43][44][48][49].

1) Positive and Negative Long-Term Effects of DBS

Information on the long-term effects of having deep brain stimulation was also provided by hospitals on their web sites. These included both positive and negative effects. Positive effects of deep brain stimulation are the reduction of movement disorder symptoms such as tremors, stiffness, and slowness of movement as well as a decrease in medication dosages needed to improve symptoms. A negative effect of deep brain stimulation is that the patient needs to take extra caution in terms of where they are and what they are doing to avoid electromagnetic interference (EMI) issues. For instance, if a DBS patient is going through airport security, they must inform the airport staff that they have a DBS device so that efforts can be made to avoid any interference issues. It is therefore recommended that DBS patients wear a medical identification bracelet stating that they have a DBS device to help avoid any issues. Also, DBS patients may not be able to undergo certain MRI procedures and should avoid areas with large magnetic fields [12][13][35][38][43][44][48].

E. DBS is Not a Cure for Movement Disorders

All hospital websites make the explicit statement that deep brain stimulation is not a cure for movement disorders and will not resolve all symptoms associated with the disorder. Rather, deep brain stimulation serves to improve symptoms and overall quality of life.

V. DISCUSSION

The 14 studied hospitals and medical centers delivered detailed information about the pre-operative protocols, risks, procedural information, after care, and long term effects. This information is summarized in Table 3.

People with Parkinson's disease, essential tremor, dystonia, Tourette's syndrome, and epilepsy are all considered ideal candidates for DBS. However, not all people who are diagnosed with these conditions are eligible for the procedure based on their symptoms. For instance, a patient with Parkinson's disease may not be eligible if their primary disabling symptom is difficulty with walking, balance, or freezing [50]. This can be problematic given that DBS is often a last resort procedure, after the patient living with a condition has exhausted all other avenues for care. DBS should be more heavily researched to resolve disabling motor symptoms, as it has become a well-established procedure for treating Parkinson's disease and other motor conditions.

A. The Important Role of Pre-Operative DBS Education

The studied hospitals and medical centers explained what the patient's should expect regarding pre-operative protocols, the procedure itself, and post-operative protocols. Providing this information is important in potentially relieving a patient's anxiety before the procedure. The most common anxieties experienced by neurosurgical patients are waiting for surgery, physical/mental harm, and results of the operation [51]. Patients who receive education prior to an elective surgical

procedure have improved outcomes and satisfaction with the surgical experience [52]. In the case of DBS, this preoperative education can come in the form of educational videos and webpages about the procedure and after care processes, or from speaking directly with the surgeon prior to surgery.

TABLE III. DEEP BRAIN STIMULATION POLICIES AND PROCEDURES

Stage	DBS as a Process and Related Risks	
	DBS as a Process	***Description***
1	Pre-Operative Protocols	- Complete quality of life and pain scales - Complete cognitive assessments - Occupational therapy and/or speech, language, and swallowing assessment - Discuss procedure with surgeon and nurses
2	Procedure	- Electrode placement - Generator placement - Device activation
3	After Care	- In hospital: Doctor will monitor patient for complications such as seizures during post-op - At home: Patient must use caution when bathing; look for warning signs such as increased redness, swelling, drainage, increase in pain, and fever >100ºF
4	Risks	- Infection - Electrodes moving - Leaking of cerebrospinal fluid - Stroke - Difficulty concentrating - Seizure - Headache - Allergic reaction to anesthesia - Heart or lung problems - Changes in personality, memory, thinking, or language skills - Pain along the device or wire - Fluid build-up around the device or wire - DBS may stop working over time - Tingling in face, arms, or legs - Slurred speech, soft voice or other problems talking or swallowing - Weakness - Balance changes - New involuntary movements - Hardware complications such as eroded lead wire

Two-thirds of a population of patients with movement disorders who have undergone DBS reported that they felt fully prepared for their surgery after receiving preoperative teaching about what to expect before and after their procedure from their nurse and surgeon [53]. It is critical that hospitals and medical centers provide educational resources to patients prior to their DBS procedure, and also for the patient's care team to show patients where they can find this information. It is common for patients to perform their own research prior to a procedure to learn more about it and what to expect. With this, it is possible for the patients to encounter false and inaccurate information that could deter them from undergoing the procedure. Hospitals and medical centers have primary responsibility in ensuring that patients know where to find the most relevant and accurate information regarding their procedure.

B. Hospitals on DBS Surgery Risks and Long-Term Effects

The 14 studied hospitals and medical centers clearly outlined that there are many risks and long-term effects associated with undergoing the DBS procedure. These risks are summarized in Table 3. Although these risks are listed for the patients to review prior to their procedure, the severity of each is not clearly described. The list of potential risks following the DBS procedure is long and as such, may be easy for patients to skim over. It is important for potential patients to truly understand the risks associated with the procedure and the extent to which DBS may affect their daily life. An interview with a DBS patient revealed that he no longer drives due to the EMI of his device with the car's computing systems, that he long longer attends sporting events due to EMI with entrance security, and that he does not hold his cell-phone within 20 inches of his head due to EMI issues [8][9]. These are major side effects that affect daily life that hospitals and medical centers do not emphasize in their informational content.

Additionally, little to no information is provided by the hospitals and medical centers about the potential for malfunctioning of the programming of the device and how to resolve it if the issue were to arise. A patient who has received DBS reported that he once experienced issues with his device after the doctors programmed his settings incorrectly, so that it was firing at twice its normal frequency, which caused him to feel like he was extremely over-caffeinated [9]. The only way for him to resolve this issue was for him to call his care team at the hospital so that they could fix it. This can be a very scary scenario for DBS patients that is almost completely out of their control.

Other issues that might arise as a result of misprogramming include: speech impairment; dyskinesia; paresthesia; autonomic side effects such as nausea and excessive sweating; gait impairment and postural instability; acute neuropsychiatric side effects such as apathy, mirthful laughter, acute mania, and acute depression; depression; mania; impulse control disorders; and cognitive side effects such as reduced verbal fluency and executive dysfunction [54]. These issues that come as a result of programming errors can impair daily functioning and are out of the patient's control. Hospitals and medical centers should more clearly outline these potential risks so that patients are prepared for these scenarios should they occur.

VI. CONCLUSION

In conclusion, the Internet has provided a mechanism by which educational resources about DBS procedures and policies at given hospitals and medical centers across the USA, can be accessed by members of the public, including potential candidate patients, their caregivers, medical and health practitioners, direct stakeholders, and indirect observers. The surgical procedure, while not without its short-term and long-term risks, is now considered a minimally invasive technique. Even if patients are eligible for the elective surgery, hospitals and medical centers emphasize, in their information resources-video, and online fact sheets, that the pros and cons of the safety risks should be considered against an individual's

personal circumstances and context. The information emphasizes the need for decisions about whether or not to undertake DBS surgery to be undertaken in consultation with a patient's physician or specialist. Importantly, while the FDA has approved DBS for some conditions like Parkinson's Disease, it does not mean it has approved DBS surgery for all types of application areas. For example, in hypothalamic DBS for obesity, effectiveness has not been proven to be robust or reproducible, though the surgery has been shown to be "reasonably safe in well-selected patients" [55].

A. Future Research

As brain implant procedures become increasingly commonplace, and informational resources continue to mature, new forms of information will proliferate allowing patients, and physicians to make more informed decisions about the future of their health. It is however, a new emerging research area in which it is required to determine whether more realistic educational resources, e.g., the use of mixed reality (such as virtual reality) may better prepare a prospective patient, or cause greater anxiety in the patient for the impending procedure under consideration, or in fact deter the patient from opting-in to the elective surgery. One thing is certain however, the videos containing DBS surgical patient testimonials provide a positive experience of a "successful" patient procedure, instead of more balanced real-world experiences by patients who experienced greater variability in the results of their DBS procedures. Messages related to safety risks are usually scrolled through in silence at the end of the DBS videos providing a different kind of experience to a first-person account.

The novelty effect of a new embedded device such as a brain implant, may well prove to be in alignment with other outcomes of the adoption of new technologies such as smartphones, but serious longitudinal analysis of a deep qualitative nature is required. A comparison of educational informative videos of hospitals and medical facilities could be done also with those virtual blogs (vblogs) of patients who are self-recording their DBS journey and uploading onto YouTube or Tik Tok. But DBS, just like Vagus Nerve Stimulation (VNS) and other brand new procedures being promoted by companies like Neuralink and Synchron, promise to draw researchers of all kinds (e.g., even lawyers and social workers) to the domain. It is especially important, that scholars from science and technology studies, sociologists and anthropologists are drawn to the biomedical field to ensure the authenticity and robustness of the patient care process, especially as informed consent will become increasingly important to prove.

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