

INFORMED CONSENT IN MATERNITY CARE: A GLOBAL PERSPECTIVE

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Human dignity is reflected, inter alia, in the ability of a human being as such, to freely form his or her personality at his or her own free will, to express ambitions and to choose the means of realizing them, to make his or her own volitional choices, not to be subjected to arbitrary coercion, the right to fair treatment by any authority or any other individual, to benefit from the inherent equality of all human beings. . . .¹

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¹ CA 2781/93 Daaka v. Carmel Hospital, 53(4) IsSC 526 (1999).

I. INTRODUCTION

From the Tuskegee experiments to the Nuremburg trials, history has not looked kindly on the forceful or harmful intrusion on an individual's right to bodily autonomy.² When egregious harm is imposed on people against their will, the public typically expresses outrage in response.³ The legal response to consent issues represented in situations like those above has been swift and decisive.⁴ But what if the intrusion is much less egregious? How far down the scale of perceived harm does the right to be free from unwanted bodily intrusion carry us? What legal remedies are available if a healthcare provider violates our right to refuse treatment or fails to provide adequate information for a routine procedure?

These are complicated theoretical questions, especially when analyzed in a legal context. To offer some insight, this Note will explore informed consent in several jurisdictions, namely the United States, India, and Israel. The Indian and Israeli jurisdiction discussions will include a general overview of the legal systems and a few additional factors to consider within those societies that may impact the quality of the informed consent process. Once a foundation for the legal framework of informed consent has been established, this Note will apply the patient scenario given below to each jurisdiction's law to see what legal remedies would have theoretically been available to the patient. At the conclusion, a promising clinical intervention designed to promote better-quality informed consent in maternity patients will be discussed.

A. Patient Scenario⁵

Sara is a twenty-five-year-old patient of Dr. A. Sara is pregnant with her first child and has gone into labor. The pregnancy has been medically unremarkable to this point, and labor has progressed normally. After laboring in the hospital for eight hours, the nursing staff informs Sara that she is ready to begin pushing through her contractions. Dr. A has not been present during the labor, but has just arrived to the delivery room. Sara pushes through two contractions. At the end of the second contraction, Dr. A tells her he will perform an episiotomy⁶ to “make room for the baby.”

² See Jayne Hardicre, *An Overview of Research Ethics and Learning from the Past*, 23 *BRIT. J. NURSING*, 483, 483–84 (2014).

³ *Id.*

⁴ *See id.*

⁵ This patient scenario is based in part on a real-life scenario that occurred in California in 2013. Brandy Zadrozny, *New Mom Begged Doc: ‘No, Don’t Cut Me!’*, *DAILY BEAST* (June 5, 2015, 5:25 AM), <http://www.thedailybeast.com/new-mom-begged-doc-no-dont-cut-me>.

⁶ *Episiotomy*, *MERRIAM-WEBSTER*, <https://www.merriam-webster.com/dictionary/episiotomy> (last visited Feb. 28, 2018) (an episiotomy is “a surgical incision of the

Sara and Dr. A have never discussed an episiotomy before at any of her prenatal visits. Though she has a general idea of what this minor procedure entails, she does not know any of the risks or alternatives available. Sara says she does not want an episiotomy and asks Dr. A if they can wait a little longer before proceeding. Dr. A is very curt with Sara. He insists that he feels the baby's head is too big and will only come out if he performs an episiotomy. He does not explain any of the risks or alternatives. At the urging of the nurses and her mother who is in the room with her, Sara does not protest further, and Dr. A performs the episiotomy. The baby is delivered without complication.

After delivery, Sara experiences discomfort which she attributes to the episiotomy. The pain persists for months. Beside physical pain, she also feels upset and violated by the episiotomy. Sara decides to make an appointment with the hospital administration to discuss the situation. The hospital administration takes note of her concerns, but offers no further help other than assuring her that her pain will probably go away in time. Feeling unsatisfied by the hospital's response, Sara decides to consult a lawyer.

II. US JURISPRUDENCE AND HEALTHCARE SYSTEM

A. US Informed Consent Generally

Understanding the process of informed consent is critical to analyzing the ethical and legal issues that may arise when a healthcare provider obtains incomplete or otherwise flawed consent from a patient. Though the US standard for informed consent varies by state, one of the two most widely recognized definitions⁷ is derived from the 1972 case *Canterbury v. Spence*.⁸ *Canterbury* stipulated that physicians must disclose to patients information that a reasonable patient would want to know.⁹ This information includes the nature of the condition or ailment, the nature of the proposed recommended treatment, the likelihood of treatment success, and other viable treatment options available to the patient.¹⁰ Though other jurisdictions follow the "reasonable physician" standard,¹¹ this Note will use the reasonable patient standard as the general US standard for informed consent.

perineum to enlarge the vaginal opening for obstetrical purposes during the birth process.”).

⁷ JESSICA BERG ET AL., INFORMED CONSENT LEGAL THEORY AND CLINICAL PRACTICE 42–55 (2nd ed. 2001).

⁸ See generally 464 F.2d 772 (D.C. Cir. 1972) (where the standard of informed consent shifted from the “professional standard” to the “patient standard” after the plaintiff became paralyzed following a botched surgery).

⁹ *Id.* at 787.

¹⁰ *Id.* at 787–88.

¹¹ BERG ET AL., *supra* note 7, at 49.

Regardless of the informed consent standard used—either reasonable physician or reasonable patient—the plaintiff must meet two additional burdens in order to demonstrate the causal link between the non-disclosure and the harm suffered.¹² First, the plaintiff must show that the procedure or technique for which the patient’s consent was inadequate actually caused the harm.¹³ The second, more challenging, burden is establishing that the provider’s failure to advise the patient of risks or alternatives caused the patient to choose (or not choose) a particular treatment.¹⁴ When examining whether the patient would have chosen differently, had the provider given proper disclosure, there is a concern that the patient may provide self-serving testimony.¹⁵ To mitigate that concern, courts have adopted a two-part objective test discussed at length in *Randall v. United States*.¹⁶ In this test, the plaintiff must first testify that they would have chosen differently had the proper disclosures been made.¹⁷ Second, the trier of fact must determine that, had the proper disclosures been made, a reasonable and prudent person in the patient’s position would also have chosen the way the patient would have.¹⁸ If both parts of this test are met, then the causal link is established.¹⁹

The method of actually disseminating required disclosures to a patient varies somewhat. One discussion of informed consent theorizes that there are two models of disclosure: “consent as an event” and “consent as a process.”²⁰ “Consent as an event” can fairly be described as a lesser-quality consent, where the patient is given only a cursory overview of the necessary information at the time the “event” is to take place.²¹ The patient is often given only moments to digest the provided information before needing to decide whether to proceed.²² In sharp contrast to this model is “consent as a process.”²³ “Consent as a process” is described as disclosures and conversations between a patient and healthcare provider that occur over time, in advance of the proposed treatment, and usually without the stress and anxiety often present at the time of the event.²⁴ Obtaining “consent as a process” provides what some consider to be better-quality informed consent because it is more inclusive to the patient in terms of the patient’s level of involvement in the decision-making process. Further, “consent as a process”

¹² JOHN SEYMOUR, *CHILDBIRTH AND THE LAW* 86 (1st ed. 2000).

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *See id.*; *see Randall v. United States*, 859 F. Supp. 22, 32 (D.D.C. 1994).

¹⁷ SEYMOUR, *supra* note 12.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *See BERGET AL.*, *supra* note 7, at 167.

²¹ *Id.* at 168.

²² *Id.*

²³ *See id.* at 171.

²⁴ *Id.* at 171–72.

enhances the patient's ability to more thoroughly and accurately retain important information regarding the condition and the available treatment options.²⁵

One final consideration is the concept of informed refusal. Informed refusal refers to situations when a patient has received all information necessary and relevant regarding a physician's proposed treatment, intervention, procedure, or medication, and does not consent.²⁶ Informed refusal is an important aspect of patient autonomy, which must be respected and honored by health care professionals.²⁷

B. Challenges to Optimal Informed Consent Specific to US Maternity Care

The unique circumstances surrounding a typical US labor and delivery can create barriers to informed consent and can make informed refusal very challenging as well.²⁸ In many instances, the information disseminated to a laboring patient may *technically* follow the informed consent legal definition, but it is done at the time of the proposed treatment rather than beforehand (more closely resembling "consent as an event" described above). Arguably, though this is unfortunately necessary in some rare cases of true medical emergencies, this style of obtaining consent does not allow the patient to have a thorough understanding of the treatment proposed and the available alternatives. Further, even in such cases of emergency, there are exceedingly few instances in which a provider is ethically and legally able to carry out procedures or interventions on a laboring patient or to administer her any medication without first obtaining thorough informed consent from her.²⁹ Barring other issues regarding questionable patient competency, the legal standard of care requires obtaining patient consent.³⁰

²⁵ BERGET AL., *supra* note 7, at 172.

²⁶ See *Informed Refusal*, 53 INT'L J. GYNECOLOGY & OBSTETRICS 84, 84–85 (1996).

²⁷ *Id.*

²⁸ Farah Diaz-Tello, *Invisible Wounds: Obstetric Violence in the United States*, 24 J. REPROD. HEALTH MATTERS 56, 56 (2016).

²⁹ Wendy Woolery, *Informed Consent Issues Throughout the Birthing Process*, 21 J. LEGAL MED. 241, 242 (2000); see also COMM. ON ETHICS, AM. C. OBSTETRICIANS & GYNECOLOGISTS, REFUSAL OF MEDICALLY RECOMMENDED TREATMENT DURING PREGNANCY 2 (2016), <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/Refusal-of-Medically-Recommended-Treatment-During-Pregnancy> (ACOG Committee opinion stating, "[p]regnancy is not an exception to the principle that a decisionally capable patient has the right to refuse treatment, even treatment needed to maintain life. Therefore, a decisionally capable pregnant woman's decision to refuse recommended medical or surgical interventions should be respected.").

³⁰ See generally Paul S. Appelbaum, *Assessment of Patients' Competence to Consent to Treatment*, 357 NEW ENG. J. MED. 1834 (2007) (for an interesting discussion from a physician's perspective on determining patient competency to consent, which is beyond the scope of this Note).

1. Communication Between Patients and Health Care Providers

Generally speaking, US women report being very satisfied with the quality of maternity care available in the United States.³¹ Despite this being the case, there is a significant portion of maternity patients who report concerns related to communication issues with their provider.³² In a landmark survey of 2,400 women, 22% reported wanting to ask their health care provider pregnancy or birth-related questions, but held back because they felt they wanted maternity care that differed from what their provider wanted.³³ This survey also shows that 23% of women refrained from asking questions because they did not want to seem “difficult.”³⁴ Nearly a third of women reported that they refrained from asking their provider questions relevant to their pregnancy because their provider seemed rushed.³⁵

2. Defensive Medicine

The issue of defensive medicine is one that lurks in the background for many professionals who work in the US maternity care system. The phrase “defensive medicine” describes a type of behavior among physicians that occurs when doctors order tests, procedures, or extra visits, or when they avoid certain high-risk patients or procedures, primarily because of concern about malpractice liability.³⁶ The feeling amongst some Obstetrician/Gynecologists (OB/GYN) is that the culture of obstetrical care has shifted over the years to reflect a more palpable awareness of the physicians’ fears of facing a malpractice suit.³⁷ One physician describes that shift by explaining that, where before a group of OB/GYNs may have spent most of their time together discussing labor management, they have replaced that conversation with how to avoid lawsuits.³⁸ This fear of facing a malpractice lawsuit seems well-founded, given that by the time they reach age 65, nearly all OB/GYN physicians will have faced a lawsuit.³⁹

³¹ EUGENE R. DECLERCQ ET AL., LISTENING TO MOTHERS III PREGNANCY AND BIRTH, XVII (2013), <http://transform.childbirthconnection.org/reports/listeningtomothers/> (80% of mothers surveyed rate the maternity care system as “good” or “excellent”).

³² *Id.* at 8.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ David Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 J. AM. MED. ASS’N, 2609, 2609 (2005).

³⁷ David King, *Medical Malpractice and the Delivery of Obstetrical Care*, 11 INT’L J. CHILDBIRTH EDUC. 30, 30 (1996).

³⁸ *Id.*

³⁹ See Anupam B. Jena et al., *Malpractice Risk According to Physician Specialty*, 365 NEW ENG. J. MED. 629, 631 (2011) (Table 1). OB/GYN physicians are categorized as

More recent works have determined that maternity clinicians who have been through a malpractice lawsuit, or who experience daily concerns of being sued, have a higher propensity for recommending cesarean sections to their patients.⁴⁰ Providers over-recommending cesarean sections to their patients is not only inappropriate in terms of those patient interactions, but it is also against the general policy recommendations made by many maternal health organizations that hospitals work to decrease their cesarean rates.⁴¹

3. Motivations to Pursue Legal Action

Seeking to better understand the motivations behind why some patients sue, researchers conducted a survey of patients and relatives of patients who had filed malpractice suits against physicians.⁴² The researchers discuss the misconception that a patient's decision to file a lawsuit against a physician is primarily done for financial gain.⁴³ In fact, their findings show that the most common reasons cited for filing a lawsuit have much more to do with dissatisfaction regarding the communication between the patient and the physician, and a strong desire to prevent the physician from harming future patients.⁴⁴

Similar research has been conducted to examine the narrower area of obstetrical malpractice.⁴⁵ The patient's perception of the interpersonal skills of their obstetrician (OB) played a part in how likely that OB was to be sued.⁴⁶ Patients of OBs who experienced the highest rates of malpractice were more likely

“high-risk” specialists. 99% of physicians who practice a high-risk specialty will face a malpractice suit by the time they reach age 65.

⁴⁰ Yvonne Cheng et al., *Litigation in obstetrics: Does Defensive Medicine Contribute to Increase in Cesarean Delivery?* 27 J. MATERNAL-FETAL NEONATAL MED. 1668, 1668–75 (2014).

⁴¹ See generally *Specifications Manual for Joint Commission National Quality Measures*, THE JOINT COMMISSION, <https://manual.jointcommission.org/releases/TJC2013A/MIF0167.html> (last visited Jan. 20, 2019). It is generally understood and recommended by ACOG, AMA, CDC, WHO, and other stakeholders in maternal health that cesarean section rates in the US are far too high. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has implemented best-practices that accredited hospitals are to follow in order to decrease their cesarean rates.

⁴² See Charles Vincent et al., *Why do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action*, 343 THE LANCET 1609, 1609 (1994).

⁴³ See *id.* at 1612.

⁴⁴ *Id.* at 1611.

⁴⁵ See generally Gerald Hickson et al., *Obstetricians' Prior Malpractice Experience and Patients' Satisfaction With Care*, 272 J. AM. MED. ASS'N, 1583 (1994) (examining the relationship between prior physician malpractice experience and patients' satisfaction with care).

⁴⁶ *Id.* at 1586.

to describe feeling rushed during prenatal visits, ignored during the labor and delivery, and to feel that explanations given by the OB during labor were inadequate.⁴⁷

4. Ethical Dilemma Faced by OB/GYN Physicians

Finally, the field of obstetrics poses an ethical dilemma not typically faced by other physician specialties.⁴⁸ Not only is the physician responsible for the care of their pregnant patient, but also for the well-being of the fetus.⁴⁹ Balancing the interests of the two patients is an extremely difficult task and can lead to profound conflicts.⁵⁰ For example, what should a physician do when a patient refuses to undergo a cesarean delivery even though the fetus is in severe distress? While the physician can seek court-ordered interventions to perform the procedure, this option is discouraged by the American Medical Association and is contrary to the constitutional underpinnings behind notions of patient autonomy.⁵¹ The alternative is to attempt to persuade the mother of the dangers of refusing to consent, although such persuasion may edge over the border into coercion and, thus, also be problematic.⁵² This leaves the physician in an incredibly unenviable position. Both the American Congress of Obstetrics and Gynecology and the American Medical Association recommend thorough counseling aimed at helping the pregnant patient understand the risks and benefits of the recommended procedure as the best choice for physicians faced with this scenario.⁵³

C. Applying the Patient Scenario Under US Law

In the US legal system, while a malpractice claim involving only a violation of informed consent may be a cause of action on which a plaintiff could prevail, it is unlikely that Sara's claim would ever make it into a courtroom to be litigated. This is because many US personal injury attorneys will not bring a claim of violation of the right to informed consent unless it is accompanied by a claim of negligent medical malpractice or some other tort.⁵⁴ Additionally, the fact

⁴⁷ Gerald Hickson et al., *supra* note 45, at 1586.

⁴⁸ See Neha A. Deshpande & Corrina M. Oxford, *Management of Pregnant Patients Who Refuse Medically Indicated Cesarean Delivery*, 5 REV. OBSTETRICS & GYNECOLOGY e144, e144–150 (2012).

⁴⁹ *Id.* at e145.

⁵⁰ *Id.*

⁵¹ *Id.* at e145–46.

⁵² *Id.* at e146.

⁵³ Deshpande & Oxford, *supra* note 48, at e149.

⁵⁴ See MARK HALL ET AL., *MEDICAL LIABILITY AND TREATMENT RELATIONSHIPS* 204 (Vicky Been et al. eds., 3rd ed. 2013).

that neither Sara nor her child suffered death or serious physical injury as a result of the incident is another obstacle to winning this kind of lawsuit in the United States.⁵⁵

Despite the realities of the legal climate described above, by applying the facts of Sara's case to a pure theory of *Canterbury* informed consent standards, it seems clear that Dr. A breached his duty to disclose the necessary information to Sara. Revisiting the reasonable patient standard under *Canterbury*, Dr. A should have disclosed: (1) the nature of the condition or ailment; (2) the nature of the proposed recommended treatment; (3) the likelihood of treatment success; and (4) other viable treatments options available to the patient (including no treatment at all).⁵⁶ While Dr. A did tell Sara that the baby's head was too big to come out (*Canterbury* element 1), and that he was going to perform an episiotomy (*Canterbury* element 2), he did not discuss the likelihood of the episiotomy being successful, or other alternatives that were available (*Canterbury* elements 3 and 4).

Even if Sara had given verbal consent to the episiotomy, the disclosures she received would still fall far below the *Canterbury* informed consent standard of care. The fact that Sara initially told Dr. A that she did not want an episiotomy raises the additional issue of Dr. A's violation of Sara's right to refuse treatment. If Dr. A had honored Sara's right to refuse the episiotomy, such refusal could not be properly considered "informed" refusal, as there was only scant disclosure regarding the first two *Canterbury* elements, and no disclosure to Sara of the last two.

In the unlikely event that Sara would be able to retain an attorney and proceed to trial, Dr. A would likely argue that an emergency exception to thorough disclosure applied, and thus relieved him of his duty. A court would not be likely to find such an argument persuasive though, as Sara was fully coherent at the time, and the available facts do not indicate that either she or her unborn baby were in physiological distress. Finally, although the disclosure fell below the reasonable patient standard of care, Sara still would bear the burden of showing that a reasonable patient in her position would have made a different choice if she had received proper disclosure.

This burden would be established using the *Randall* test for causation. First, had one been presented to her, Sara would need to testify that she would have chosen an alternative (including no episiotomy at all). Second, the court would need to find that a reasonable and prudent patient in Sara's position would have been likely to choose an alternative over the proposed episiotomy (this is where the analysis becomes more challenging). Episiotomies are among the most common procedures performed in the United States, occurring in approximately 30–35% of all vaginal births.⁵⁷ Despite their widespread use, medical literature

⁵⁵ See *id.*

⁵⁶ *Canterbury*, 464 F.2d at 787.

⁵⁷ Katherine Hartmann et al., *Outcomes of Routine Episiotomy A Systematic Review*, 293 J. AM. MED. ASS'N, 2141, 2141 (2005).

has shown for well over two decades that not only should episiotomies not be routinely performed, but that episiotomy administration often leads to worse patient outcomes than available alternatives.⁵⁸ While the continued use of episiotomies by some providers—despite strong evidence contraindicating such practice—is a separate discussion, the poorer subsequent patient outcomes factor is relevant here. Under the *Canterbury* requirements for disclosures, Dr. A should have disclosed all of the risks inherent in the procedure. It seems likely that under the circumstances, a reasonable and prudent patient in Sara’s position, having received the proper disclosures and being aware of the benefits, risks, and alternatives, would arguably have chosen to refuse an episiotomy. If Sara could persuade a court of this, then causation would be established, and she would prevail on the claim.

III. INDIAN JURISPRUDENCE AND HEALTHCARE SYSTEM

India has a common law legal system consisting of a both a constitution and an independent judiciary.⁵⁹ The highest court in the judiciary is the Supreme Court of India, and each state has its own High Court.⁶⁰ India gained independence in 1947, decisions made by the Privy Council in London before that time are still binding in India unless the Indian Supreme Court has overruled the decision.⁶¹

Despite India’s reputation among some scholars for being a highly litigious country, litigation rates are actually low when compared to neighboring Asian countries.⁶² This is true even when taking into account the use of tribunals and non-governmental forums for mediation in civil suits.⁶³ Scholars have pointed to several challenges within the Indian legal system that likely contribute to low relative litigation rates and increase the perception that the country is highly litigious.⁶⁴ First, there is a severe shortage of judges.⁶⁵ To illustrate this point, in 1998, the United States had approximately ten judges per 100,000 citizens.⁶⁶ In 1995, India had just one judge per 100,000 citizens.⁶⁷ The second factor commonly cited is the frequent civil court delays and high court fees facing

⁵⁸ Hartmann et al., *supra* note 57, at 2147.

⁵⁹ *Legal System: Indian Law*, UNIV. OXFORD, <https://ox.libguides.com/c.php?g=422964&p=2888488> (last visited Feb. 28, 2018).

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² See Marc Galanter, *Part I Courts, Institutions, and Access to Justice: “To the Listed Field . . .”: The Myth of Litigious India*, 1 JINDAL GLOB. L. REV. 65, 69.

⁶³ See *id.* at 70–71.

⁶⁴ See *id.*

⁶⁵ *Id.*

⁶⁶ Galanter, *supra* note 62, at 71.

⁶⁷ *Id.*

potential litigants.⁶⁸ For example, in the Calcutta High Court, an average case can be as long as 15 to 20 years from start to finish, not including the possibility of an additional three to six years if the case is appealed.⁶⁹

Beside the logistical hurdles facing civil litigants in India, the socioeconomic and cultural challenges create additional barriers to meaningful justice for patients.⁷⁰ India faces high illiteracy rates, significant challenges related to health care delivery systems, limited national resources for health care services generally, health care provider shortages, and a lack of enforceable regulation of health care facilities and providers.⁷¹ The Medical Council of India (MCI) has been roundly criticized both for failing to create a code of conduct for hospitals and clinics, as well as for allowing claims alleging unethical behavior by physicians to go unchecked.⁷²

When it comes to pursuing a medical malpractice claim against a physician, there are yet further obstacles for a plaintiff to overcome. In India, patients are routinely denied access to their medical records, including basic information like their diagnosis and prescribed treatment.⁷³ Locating an expert to testify on a party's behalf is exceedingly difficult, stemming from the physician shortage.⁷⁴ Finally, there exists a strong gender imbalance within Indian culture in terms of gender norms and the status of women within Indian society.⁷⁵ With nearly 83% of all allopathic physicians in India being male,⁷⁶ these societal norms can lead to an even more pronounced imbalance in the power dynamic between a male physician and his female patient. In clinical settings, researchers have noted

⁶⁸ Galanter, *supra* note at 70.

⁶⁹ Bhatnagar v. Surrendra Overseas Ltd., 52 F.3d 1220, 1228 (3d Cir. 1995).

⁷⁰ See generally Nathan Cortez, *A Medical Malpractice Model for Developing Countries?*, 4 DREXEL L. REV. 217 (2011) (Providing a detailed analysis of cultural and socio-economic challenges in Indian medical malpractice).

⁷¹ See generally Leena V. Gangolli et al., *Review of Healthcare in India* (Centre for Enquiry Into Health and Allied Themes. ed., 2005) ; see Cortez, *supra* note 70.

⁷² PARLIAMENT OF INDIA, NINETY-SECOND REPORT: THE FUNCTIONING OF MEDICAL COUNCIL OF INDIA (MINISTRY OF HEALTH AND FAMILY WELFARE) 46–47 (2016), <http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Health%20and%20Family%20Welfare/92.pdf>.

⁷³ Nathan Cortez, *Recalibrating the legal risks of cross-border health care*, 10 YALE J. HEALTH POL'Y L. & ETHICS 1, 28–29; see generally Jai Anant Dehadrai, *Greed and the Rise of Medical Malpractice in India*, THE TIMES OF INDIA (Aug. 23, 2016) <https://blogs.timesofindia.indiatimes.com/the-irreverent-lawyer/greed-and-the-rise-of-medical-malpractice-in-india/> (for an Indian lawyer's perspective on healthcare facility compliance with producing medical records when requested, and the Indian system of regulation and accountability for healthcare facilities and providers).

⁷⁴ Cortez, *supra* note 70, at 227.

⁷⁵ See generally A. Weitzman, *Women's and Men's Relative Status and Intimate Partner Violence in India*, 40 POPULATION AND DEV. REV. 55 (2014).

⁷⁶ Krishna Rao et al., *Composition and distribution of the health workforce in India: estimates based on data from the National Sample Survey*, 5 WHO SE. ASIA J. PUB. HEALTH 133, 136 (2016).

that there is a strong tendency among Indian physicians to generally hold paternalistic views towards their patients.⁷⁷ This tendency is even more evident when the patient is female.⁷⁸

A. Informed Consent in India

The backlog of cases and general inefficiencies in the Indian judicial system mean that there is an underdeveloped body of law regarding legal standards for informed consent. The seminal case on point for establishing professional negligence (including negligence in the medical context) is the 1957 English case *Bolam v. Friern Hospital Management Committee*.⁷⁹ The *Bolam* test was revisited and succinctly explained in the 2005 Indian Supreme Court case *Jacob Mathew v. State of Punjab*:

In tort, it is enough for the defendant to show that the standard of care and the skill attained was that of the *ordinary competent medical practitioner exercising an ordinary degree of professional skill*. The fact that a defendant charged with negligence acted in accord with the general and approved practice is enough to clear him of the charge. . . . A mere deviation from normal professional practice is not necessarily evidence of negligence. Let it also be noted that a mere accident is not evidence of negligence. So also an error of judgment on the part of a professional is not negligence per se. . . . The medical professional is often called upon to adopt a procedure which involves higher element of risk, but which he honestly believes as providing greater chances of success for the patient rather than a procedure involving lesser risk but higher chances of failure. Which course is more appropriate to follow, would depend on the facts and circumstances of a given case. *The usual practice prevalent nowadays is to obtain the consent of the patient or of the person in charge of the patient if the patient is not in a position to give consent before adopting a given procedure*. So long as it can be found that the procedure which was in fact adopted was one which was acceptable to medical

⁷⁷ See R.M. Yousuf et al., *Awareness, Knowledge and Attitude Towards Informed Consent Among Doctors in Two Different Cultures in Asia: a Cross-sectional Comparative Study in Malaysia and Kashmir, India*, 48 SING. MED. J. 559, 559 (2007); see also Malene Tanderup et al., *Informed Consent in Medical Decision-Making in Commercial Gestational Surrogacy: a Mixed Methods Study in New Delhi, India*, 94 ACTA OBSTETRICIA ET GYNECOLOGICA SCANDINAVICA 465, 470–71 (2015).

⁷⁸ R.M. Yousuf et al., *supra* note 77, at 561–62.

⁷⁹ *Bolam v. Friern Hospital Management Committee* (1957) 1 WLR 582 (UK).

science as on that date, the medical practitioner cannot be held negligent merely because he chose to follow one procedure and not another and the result was a failure.⁸⁰

The *Mathew* opinion states that even a low level of care will not be found to fall below the standard of care if another “ordinary competent medical professional” might have made the same decision under the same circumstances.⁸¹

After *Mathew* was decided in 2005, another case offering a more in-depth analysis of informed consent issues came to the Indian Supreme Court in 2008. In *Samira Kohli v. Dr. Prabha Manchanda & Anr*, a patient sought treatment for prolonged menstrual bleeding.⁸² Her doctor recommended a laparoscopic procedure to make an affirmative diagnosis.⁸³ While the adult patient was under general anesthesia, and with consent only from the patient’s mother, the doctor decided to remove the patient’s uterus, fallopian tubes, and ovaries.⁸⁴ The Court looked to a wide variety of foreign jurisdictions to analyze the issue of consent in such a scenario.⁸⁵ Finding the *Canterbury* holding to impinge too greatly on a physician’s autonomy, the case established a middle-of-the-road approach between the reasonable patient standard of *Canterbury* and the *Bolam* “ordinary physician” approach.⁸⁶ Citing the extreme poverty and low levels of education amongst the Indian population, the Court sought to allow physicians the right to use their judgment when making disclosures to patients without allowing the kind of overt and flagrant action that the surgeons took against the patient at hand.⁸⁷ The Court summarized its holding as follows:

(i) A doctor has to seek and secure the consent of the patient before commencing a “treatment” (the term “treatment” includes surgery also). The consent so obtained should be real and valid, which means that: the patient should have the capacity and competence to consent; *his consent should be voluntary; and his consent should be on the basis of adequate information concerning the nature of the treatment procedure, so that he knows what is consenting to.*

(ii) The “adequate information” to be furnished by the doctor (or a member of his team) who treats the patient, should enable the patient to make a balanced judgment as to whether he should

⁸⁰ *Mathew v. State of Punjab*, AIR 2005 SC 3180 (emphasis added).

⁸¹ *Id.*

⁸² *Kohli v. Manchanda*, AIR 2008 SC 1385.

⁸³ *Id.* ¶ 2.

⁸⁴ *Id.* ¶ 3.

⁸⁵ *Id.* ¶¶ 15–33.

⁸⁶ *Id.* ¶ 21.

⁸⁷ *Kohli*, AIR 2008 SC 1385, ¶ 32.

submit himself to the particular treatment as to whether he should submit himself to the particular treatment or not. *This means that the Doctor should disclose (a) nature and procedure of the treatment and its purpose, benefits and effect; (b) alternatives if any available; (c) an outline of the substantial risks; and (d) adverse consequences of refusing treatment. . . .*

(v) The nature and extent of information to be furnished by the doctor to the patient to secure the consent need not be of the stringent and high degree mentioned in *Canterbury* but should be of the extent which is accepted as normal and proper by a body of medical men skilled and experienced in the particular field. *It will depend upon the physical and mental condition of the patient, the nature of treatment, and the risk and consequences attached to the treatment.*⁸⁸

Although this case appeared to be a landmark case on the issue of informed consent, the Indian Supreme Court avoided the opportunity to use the parameters laid out in the *Kohli* decision the following year when deciding *Malay Kumar Ganguly v. Sukumar Mukherjee*.⁸⁹

In *Ganguly*, the patient was prescribed daily injections of long-lasting steroids to treat a rash.⁹⁰ The patient's husband, himself a physician researcher at Ohio State University, questioned the high dosage, but was assured by his wife's physician that he treated patients with that dose often and described its effects as "magic."⁹¹ Although the husband felt unsure about the dosage, he also understood that the Indian culture gives great deference to doctors.⁹² Not wanting to cause any discord, he did not question the doctor further, and his wife began taking the medication as prescribed.⁹³ However, her condition continued to deteriorate.⁹⁴ Despite this, the physicians and staff at the hospital continued to give her the steroid injections.⁹⁵ Ultimately, the patient developed secondary infections as a

⁸⁸ *Id.* (emphasis added) (Despite the holding, the physicians in this case were let off quite leniently by the Supreme Court. The Court cited that under the facts, the doctors had exceeded the patient's consent, but had acted in good faith, and with the patient's well-being in mind).

⁸⁹ *Ganguly v. Mukherjee*, 2009 9 SCC 221.

⁹⁰ Gayathri Vaidyanathan, *A Landmark Turn in India's Medical Negligence Law*, N.Y. TIMES: INDIA INK (Oct. 31, 2013, 1:32 PM), <https://india.blogs.nytimes.com/2013/10/31/a-landmark-turn-in-indias-medical-negligence-law/>.

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Ganguly*, 2009 9 SCC 221, at 2.

result of the excessive injections, and she died.⁹⁶ Experts at trial concluded that, had she been taken off of the steroid injections immediately and her condition been closely monitored, she would almost certainly have survived.⁹⁷

The patient's husband worked tirelessly to pursue the case in India.⁹⁸ Flying back and forth between his job in Columbus and India, he spent ten years and thousands of dollars trying to convince the Indian courts that the negligent treatment his wife had been subjected to was worthy of a claim against the physicians and hospital.⁹⁹ He gathered a team of international expert witnesses and used his knowledge as a physician to persuade the court to finally hear his case.¹⁰⁰ The Indian Supreme Court decided the case in 2009, and he spent another four years fighting for damages.¹⁰¹ Though in the end he won an award of approximately \$1 million USD, the ordeal caused him to lose his job at Ohio State, his home in Columbus, and nearly fifteen years of his life fighting through the Indian court system.¹⁰²

When addressing the issue of informed consent in the *Ganguly* opinion, the Court merely stated in dicta that:

Doctors increasingly must engage with patients during treatments especially when the line of treatment is a contested one and hazards are involved. Standard of care in such cases will involve the duty to disclose to patients about the risks of serious side effects or about alternative treatments. *In the times to come, litigation may be based on the theory of lack of informed consent.* A significant number of jurisdictions, however, determine the existence and scope of the doctor's duty to inform based on the information a reasonable patient would find material in deciding whether or not to undergo the proposed therapy. [Citations to US cases omitted]. In this respect, the only reasonable guarantee of a patient's right of bodily integrity and self-determination is for courts to apply a stringent standard of disclosure in conjunction with a presumption of proximate cause. At the same time, a reasonable measure of autonomy for the doctor is also pertinent to be safeguarded from unnecessary interference.¹⁰³

⁹⁶ Ganguly, 2009 9 SCC 221, at 2.

⁹⁷ *Id.* at 48–49; Vaidyanathan, *supra* note 90.

⁹⁸ Vaidyanathan, *supra* note 90.

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ Ganguly, 2009 9 SCC 221, at 45.

This language merely offers guidance to physicians in their interactions with patients, but fails to establish a cause of action based solely on a theory of inadequate informed consent procedures. As with the United States, it seems that this claim would only be brought with another tort cause of action in a medical malpractice claim.

B. Applying the Patient Scenario Under Indian Law

Imagining Sara's scenario taking place in an Indian hospital first requires a significant change of perspective regarding the underlying social expectations and power dynamics. To begin, Sara's physician, Dr. A, is male. Understanding that there are millennia-old gender norms and expectations in Indian culture, it is almost certain that any disagreement about a proposed intervention during childbirth—like an episiotomy—would be very difficult for a laboring patient to broach with her male physician. Next, the deference given to physicians in India is arguably even greater than it is in the United States. As the *Ganguly* case demonstrated, even a US-trained male physician was hesitant to question an Indian doctor's proposed treatment for his wife. This reluctance to question the physician would likely be even more pronounced in a young female patient with no medical training.

It also seems unlikely that the average maternity patient in India would have the financial means to pursue any lawsuit, especially one that was based on receiving inadequate disclosures regarding a common procedure performed during childbirth. Even if Sara was able to bring her claim before a court, comparing the factual circumstances present in *Ganguly* with those in the patient scenario used here, it seems unlikely that an Indian court would be sympathetic to Sara's claim. This is particularly true because the *Ganguly* court failed to establish inadequate informed consent as a cause of action. Having no other cause of action other than the informed consent claim, Sara would not likely be able to retain an attorney, and thus would not be successful in bringing a claim against Dr. A under Indian law.

IV. ISRAELI JURISPRUDENCE AND HEALTHCARE SYSTEM

Israel is a parliamentary democracy with a common law legal system.¹⁰⁴ After gaining independence in 1948, Israel continued to use a combination of the two previous legal systems, Ottoman and English common law, for a period of time.¹⁰⁵ In the first years after independence, Israel underwent a period of

¹⁰⁴ *Introduction to Israel's Legal System*, LIBR. OF CONGRESS, <https://www.loc.gov/law/help/legal-research-guide/israel.php> (last updated June 9, 2015).

¹⁰⁵ A. Barak, *Some Reflections on the Israeli Legal System and Its Judiciary*, ELECTRONIC J. COMP. L., Apr. 2002, § 1.

stabilization during which time the country experienced a massive influx of citizens and developed a system of Basic Laws.¹⁰⁶ These Basic Laws were meant to serve as a preliminary outline upon which an Israeli Constitution would eventually be born.¹⁰⁷

In the 30 years following this initial period of expansion, nearly all of the previous Ottoman law was abolished, and Israel continued to codify private law.¹⁰⁸ It was also during this time that Israel began to more fully develop the Basic Laws, and the Israeli Constitution began to take shape.¹⁰⁹ With the continued development of the Constitution, Israel enacted a statute in 1980 which severed the formal link to the English common law system.¹¹⁰ As Israel continued to build its own common law system, it was decided that judicial decisions of first impression, “should be filled by analogy, and in its absence by reference to the principles of liberty, justice, equity, and peace of Israel’s heritage” rather than English common law.¹¹¹

For the average Israeli, access to civil redress via the judicial system is a fairly straightforward process. The court fees are set at 2.5% of the value of the relief sought,¹¹² and the attorney’s fees in tort claims are typically paid on a contingent basis.¹¹³ In terms of modern judicial efficiency, Israel ranks similarly to other common law countries, with the average trial taking just under 300 days and the country having about nine judges per 100,000 citizens.¹¹⁴

In terms of Israel’s health care system, the country has utilized national health insurance (NHI) since 1995, and the Ministry of Health oversees the administration of the program.¹¹⁵ The coverage given to individuals through NHI is fairly comprehensive, including services for “hospital, primary, and specialty care, prescription drugs, certain preventive services, mental health care, dental

¹⁰⁶ Barak, *supra* note 105.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ Barak, *supra* note 105.

¹¹² Talia Fisher & Issi Rosen-Zvi, It’s for the Judges to Decide: Allocation of Trial Costs in Israel Report on Israel, in *COST AND FEE ALLOCATION IN CIVIL PROCEDURE: A COMPARATIVE STUDY* 182 (Mathias Reimann ed., 2012) (Referencing Israeli civil procedure requirements for caps on court fees).

¹¹³ *Id.*; *Medical Malpractice Claims in Israel*, GROSS ORAD SCHLIMOFF & CO., <http://www.goslaw.co.il/list.asp?categoryId=288&id=666> (last visited Feb. 28, 2018) (for an Israeli firm newsletter explaining court fees and attorney fee structure in medical malpractice claims).

¹¹⁴ Limor Zer-Gutman, *The Effects of the Shortage of Judges in Israel*, 7 *OÑATI SOCIO-LEGAL SERIES* 809, 814–16 (2017).

¹¹⁵ *The Israeli Healthcare System*, THE COMMONWEALTH FUND, <http://international.commonwealthfund.org/countries/israel/> (last visited Feb. 28, 2018) [hereinafter *The Israeli Healthcare System*].

care for children, and other services.”¹¹⁶ Individuals may also choose to purchase additional private health insurance on a voluntary basis to provide coverage for services not covered by NHI.¹¹⁷ Though this participation in private health insurance is not compulsory, most individuals choose to get additional coverage.¹¹⁸

Israel’s healthcare system has been ranked very high in terms of efficiency.¹¹⁹ This efficiency was achieved even while spending a far lower percentage of its GDP on healthcare compared to other countries, including the United States, which ranked much lower in healthcare efficiency but spent a far higher percentage of its GDP on healthcare.¹²⁰ While some Israeli citizens have expressed concerns or dissatisfaction with specific areas of NHI, 89% of the population is either satisfied or very satisfied with the NHI health plans available and health system generally.¹²¹

In terms of direct patient care, many of the specific kinds of communication problems found in countries with high illiteracy rates and high poverty levels are not prevalent in Israel. Generally speaking, Israelis are very highly educated,¹²² and the World Bank has classified Israel as a high-income nation.¹²³ Though recent statistics show that about one in five Israelis are technically living in poverty,¹²⁴ that number has declined since 2009.¹²⁵ Overall,

¹¹⁶ *The Israeli Healthcare System*, *supra* note 115.

¹¹⁷ *Id.*

¹¹⁸ Shuli Brammli-Greenberg et al., *2016 Healthcare Survey*, MYERS-JDC-BROOKDALE, <http://brookdale.jdc.org.il/en/summary-the-11th-consumer-survey-on-israels-healthcare-system/> (last visited Feb. 26, 2019) (84% of Israelis have supplemental insurance).

¹¹⁹ Ronny Linder-Ganz et al., *Israel’s Healthcare System Ranked Fourth in the World; U.S. Trails Behind*, HAARETZ (Aug. 28, 2013, 8:13 PM), <https://www.haaretz.com/israel-news/.premium-1.544034>.

¹²⁰ *The Israeli Healthcare System*, *supra* note 115 (Israel spends under 8%); *National Health Expenditure Data*, CTR. MEDICARE & MEDICAID SERV., <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (last updated Dec. 11, 2018, 10:44 AM) (while the US spends nearly 18%).

¹²¹ Brammli-Greenberg et al., *supra* note 118.

¹²² *2016 Population with tertiary education*, ORG. ECON. COOPERATION & DEV., <https://data.oecd.org/eduatt/population-with-tertiary-education.htm> (last visited Feb. 26, 2019).

¹²³ *Israel*, THE WORLD BANK, <https://data.worldbank.org/country/israel?view=chart> (last visited Feb. 26, 2019).

¹²⁴ Nehemia Shtrasler, *Fuzzy Math Exaggerates Israel’s Working-poor Problem*, HAARETZ (Dec. 15, 2015 2:55 AM), <https://www.haaretz.com/opinion/.premium-1.691766?v=98AFF2BAF151F4B81301C55CCA12F8C4> (for an interesting perspective on why the poverty level is actually much lower than what is being reported by the National Insurance Institute of Israel).

¹²⁵ NAT’L INS. INST. OF ISR., REPORT ON THE DIMENSIONS OF POVERTY AND SOCIAL GAPS, 2014 7,

education rates are high, illiteracy rates are low,¹²⁶ and Israel has a fairly efficient legal system.

Despite being a highly educated society, Israeli patients still face paternalistic attitudes among physicians and defensive medicine practices among health care providers.¹²⁷ These challenges present a different kind of communication barrier than the type found in impoverished nations like India. A national survey conducted in 2012 found that 60% of Israeli physicians across a spectrum of specialties practice defensive medicine on a *daily* basis.¹²⁸ Further, 40% of the physicians surveyed admitted to viewing every patient they treat as a potential legal threat, and 21% stated they are less likely to be frank with their patients as a result of fear of litigation.¹²⁹

Shared decision-making (SDM) is one construct that has been offered by researchers (both in Israel and elsewhere) in an attempt to bridge communication gaps between physicians and patients.¹³⁰ SDM is defined as, “the attempt to involve patients in decision-making tasks, especially where decisions, in the face of uncertain or equivocal evidence of benefit, are sensitive to personal preferences.”¹³¹ SDM has both ethical and practical benefits directly related to the driving purpose behind informed consent. The practical benefits include: “better knowledge about treatment options, more realistic expectations concerning disease course and treatment, improved adherence, enhanced patient satisfaction, and sometimes a better clinical outcome.”¹³²

A. Informed Consent in Israel

Israeli Parliament (known as The Knesset) enacted the Patient’s Rights Law in 1996.¹³³ The section specifically addressing informed consent reads as follows:

https://www.btl.gov.il/English%20Homepage/Publications/Poverty_Report/Documents/oni_2014-e.pdf.

¹²⁶ *The World Factbook*, CENT. INTELLIGENCE AGENCY, <https://www.cia.gov/library/publications/the-world-factbook/geos/is.html> (last visited Feb. 26, 2019).

¹²⁷ Elad Asher et al., *Defensive Medicine in Israel—A Nationwide Survey*, 7 PLOS ONE 1, 6 (2012); see Michael L. Gross, *Paternalistic attitudes: Autonomy and Paternalism in Communitarian Society Patient Rights in Israel*, 29 HASTINGS CTR. REP. 13, 13 (1999).

¹²⁸ Asher et al., *supra* note 127, at 3.

¹²⁹ *Id.*

¹³⁰ Talya Miron-Shatz et al., *Shared decision-making in Israel: status, barriers, and recommendations*, 1 ISR. J. HEALTH POL’Y RES. 1, 1(2012).

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Informed Consent for Medical Treatment*, THE SOC’Y FOR PATIENTS RIGHTS IN ISR., <http://www.patients-rights.org/index.aspx?id=4375> (last visited Feb. 26, 2019); *Patient’s Bill of Rights*, ST. OF ISR. MINISTRY OF HEALTH, <https://www.health.gov.il/English>

You have the right to receive an appropriate and clear explanation about your medical condition, about treatment options that are available for you and their alternatives, risks, prospects and potential side effects, including those relating to refraining from treatment. It is important that you will provide the care provider with information about your medical history, so that the diagnosis and treatment offered to you will be appropriate.

You have the right to refuse treatment to which you did not give consent (except for exceptional cases prescribed by law).

You have the right to appoint a proxy, who will have the authority to consent to medical treatment in the event that you become unable to do so.¹³⁴

In *Daaka v. Carmel Hospital*, the Israeli Supreme Court sitting as the court for civil appeals discussed the issue of informed consent at length.¹³⁵ The timing of this case is of particular relevance. The incident at issue took place before the implementation of the Patient's Rights Law in 1996, but the case was decided in 1999.¹³⁶ While the opinions explicitly state that the issues of the case could not be decided on the new law due to the events at issue having occurred before its enactment, the rationale behind the holding and the long passages of dicta seem quite deferential to the underlying principles of patient autonomy behind the new law.¹³⁷

Appellant in the case had been experiencing shoulder pain, but was at the hospital for an operation on her leg.¹³⁸ After being administered sedatives on the day of her leg operation, appellant was asked to sign a consent form so the surgeon could instead biopsy her shoulder.¹³⁹ The surgeon felt the biopsy was

/Topics/RightsInsured/Pages/patient_rights.aspx (last visited Feb. 28, 2018) [hereinafter *Patient's Bill of Rights*].

¹³⁴ *Patient's Bill of Rights*, *supra* note 133.

¹³⁵ *Daaka*, 53(4) IsSC 526, § 5.

¹³⁶ *Id.*

¹³⁷ *Daaka*, 53(4) IsSC 526, § 20 (Justice Or stating: "Parenthetically, it should be noted, in order to provide a complete picture, that in 1996, the Patient's Rights Law was enacted. The purpose of the law is 'to establish the rights of a person applying for, or receiving medical treatment and to protect his or her dignity and privacy.' Sec. 1. The law prescribes, inter alia, a detailed arrangement regulating the subject of the patient's informed consent to medical treatment Sec 13–15. This law does not apply in our case, given that it was enacted after the biopsy was performed on the appellant.").

¹³⁸ *Id.* § 1.

¹³⁹ *Id.*

more urgent than the other procedure she was scheduled for.¹⁴⁰ The surgery on her leg did not occur that day, and the biopsy that the surgeon obtained from appellant's shoulder was unremarkable, but appellant experienced increased pain and stiffness in her shoulder following the procedure.¹⁴¹ Appellant underwent several non-surgical treatments from the same surgeon for the stiffness in her shoulder, but none were successful.¹⁴²

Appellant sought damages against the physician both for negligently performing the operation without her consent, and for medical negligence in the physician's decision to perform the biopsy and the subsequent unsuccessful treatments for the stiffness.¹⁴³ The trial court dismissed all negligence claims.¹⁴⁴ When discussing the issue of informed consent, the trial judge reasoned that because the patient was aware of the issue with her shoulder, she could not have been surprised that the physician chose to perform the biopsy rather than the agreed upon leg operation.¹⁴⁵ The trial judge further stated that appellant had failed to establish a causal connection between the alleged negligence and the surgeon's failure to provide her with information about the shoulder procedure.¹⁴⁶

On appeal, appellant made several arguments.¹⁴⁷ The first argument was that even though the original complaint did not cite battery as a cause of action, the trial court erred in not considering it, as the facts of the claim satisfied the elements.¹⁴⁸ Next, appellant contended that the trial court erred in rejecting her claim that she did not consent to the shoulder procedure and argued that her prior knowledge of her shoulder injury did not preclude a claim against the surgeon for performing a different operation than the one she agreed to.¹⁴⁹ Finally, she argued that the resulting stiffness and pain after the unconsented to procedure was performed shifted the burden of proving the absence of negligence onto the respondents under a *res ipsa loquitur* theory.¹⁵⁰

The majority opinion disregarded the claim of battery, agreeing that the trial court had correctly proceeded in analyzing the facts under a negligence theory.¹⁵¹ Though the Court did not find the medical decisions of the respondents to be negligent, it did find that they were negligent regarding the claim of informed consent.¹⁵² Outlining elements of satisfactory informed consent

¹⁴⁰ *Daaka*, 53(4) IsSC 526, § 20.

¹⁴¹ *Id.*

¹⁴² *Id.* § 1.

¹⁴³ *Id.*

¹⁴⁴ *Id.* § 2.

¹⁴⁵ *Daaka*, 53(4) IsSC 526, § 2.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* § 3.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Daaka*, 53(4) IsSC 526, § 3.

¹⁵¹ *Id.* § 6.

¹⁵² *Id.* § 7.

identical to the reasonable patient standards laid out in *Canterbury*, the Court held:

[f]or a patient's consent to medical treatment to his or her body to be regarded as 'informed consent,' the patient must receive appropriate information regarding his or her condition, the nature of the treatment recommended and its purpose, the risks and prospects entailed, and the reasonable alternatives to the treatment proposed.¹⁵³

The Court went on to state that the consent form Appellant had signed after being sedated and just before the shoulder procedure was inadequate, citing Dieter Giesen's analysis of the inadequacy of obtaining consent in this manner.¹⁵⁴

Under this standard of informed consent, the Court held that respondents were negligent in their actions (and inactions) preceding the shoulder surgery.¹⁵⁵ Specifically, they were negligent because they failed to disclose the need for the biopsy to appellant, failed to disclose risks of the biopsy procedure itself (including paralysis in this case), did not provide timely notice of the intention to postpone her leg procedure, and obtained consent while she was sedated.¹⁵⁶ Moreover, while the surgeon urgently felt the need to perform the biopsy, the procedure could have easily been postponed without the patient suffering any harm, negating any tendency to show that an emergency exception to thorough informed consent would apply.¹⁵⁷

On the issue of causation, the Court discussed the various tests that can be used to make a determination.¹⁵⁸ Ultimately, the majority held that an affirmative decision on which test to use was unnecessary, as under either an objective or a subjective standard, the patient most likely would have made the choice to allow the surgeon to perform the biopsy.¹⁵⁹ Despite electing not to adopt a particular causation test, Justice Or, who authored the majority opinion, voiced his preference for the subjective test.¹⁶⁰ Finding that appellant would have likely chosen the procedure under either test, causation was not established between the respondent's failure to obtain informed consent and the physical and emotional

¹⁵³ *Daaka*, 53(4) IsSC 526, § 7.

¹⁵⁴ *Id.*; DIETER GIESEN, INTERNATIONAL MEDICAL MALPRACTICE LAW: A COMPARATIVE LAW STUDY OF CIVIL LIABILITY ARISING FROM MEDICAL CARE 393 (1988).

¹⁵⁵ *Daaka*, 53(4) IsSC 526, § 11.

¹⁵⁶ *Id.* § 7.

¹⁵⁷ *Id.* § 5.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.* § 7.

¹⁶⁰ *Daaka*, 53(4) IsSC 526, § 7.

damage the appellant suffered.¹⁶¹ As causation was not established, appellant could not recover damages under this theory.¹⁶²

Interestingly though, the Court then turned to the difficult task of balancing the desire to honor patient autonomy with the challenge of achieving a justiciable and coherent precedent for future claims.¹⁶³ After a lengthy discussion of the pros and cons, Justice Or concluded that the appellant *was* entitled to recover for the violation of her autonomy as a patient, and that this violation of her rights would be considered *its own cause of action*, and appellant was entitled to non-pecuniary damages.¹⁶⁴ The Court ordered that appellant be awarded NIS 15,000 (approximately \$4,300).¹⁶⁵ Besides stressing the value of patient autonomy when arriving at this conclusion, Justice Or cited that the relationship between the physician and patient not only rose to the level of a special relationship in terms of tort law, thus raising the duty of care, but that the physician-patient relationship can be analyzed under theories of contract law by courts as well.¹⁶⁶ This case was monumental in its use of the legal system to create a cause of action for a patient solely based on a violation of their autonomy. Therefore, Israel stands at the far end of the spectrum of the jurisdictions analyzed in this Note in terms of providing a robust legal remedy to a patient who has not received proper informed consent disclosures.

With such a strong stance taken by the Israel Supreme Court on the importance of patient autonomy, the next logical question is whether the potential threat of legal ramifications might have made any positive impact on the quality of informed consent in the Israeli medical system. Three years after *Daaka*, a study was conducted among Israeli patients who were scheduled to undergo invasive procedures.¹⁶⁷ Half of the patients could not remember receiving explanations about the risks of the recommended procedure, and two-thirds could not remember their physician discussing available alternative treatments.¹⁶⁸ Additionally, researchers found that physicians were resistant to attempts to improve informed consent.¹⁶⁹

¹⁶¹ *Daaka*, 53(4) IsSC 526, § 12.

¹⁶² *Id.*

¹⁶³ *Id.* § 28.

¹⁶⁴ *Id.* (although the actual amount of compensation is quite small).

¹⁶⁵ *Id.* § 29 (exchange rate calculation done on Feb. 28, 2018 using data available at <https://www.exchange-rates.org/history/ILS/USD/T>).

¹⁶⁶ *Daaka*, 53(4) IsSC 526, § 23.

¹⁶⁷ See generally Mayer Brezis et al., *Quality of Informed Consent for Invasive Procedures*, 20 INT'L J. FOR QUALITY IN HEALTH CARE 352 (2008).

¹⁶⁸ Brezis et al., *supra* note 167, at 352.

¹⁶⁹ *Id.*

B. Applying the Patient Scenario Under Israeli Law

Sara would almost certainly be successful in bringing a lawsuit under Israeli law. As with the analysis under US law, the disclosures Dr. A made to Sara about the proposed episiotomy do not satisfy the required disclosures described in *Daaka* (which mirror the *Canterbury* elements). Because these disclosures were inadequate, and Sara suffered emotional distress as a result, she would be able to collect modest damages.

Despite litigation success being probable, the question still remains whether the potential for a modest award would warrant the time and money needed to pursue a claim. As with the analysis under US law, Israeli attorneys are paid on a contingency basis. With only a modest damages award being possible, it seems unlikely (even with the strong likelihood of claim success) that an attorney would be willing to devote the amount of time and resources necessary to take Sara on as a client. Thus, even with Israeli law being the most reverent to notions of patient autonomy of the three jurisdictions, the ultimate outcome remains similar to what would be seen under US law: little *meaningful* recourse through the legal system.

V. CONCLUSION

A. Summary of Cross-Jurisdictional Informed Consent

The legal system has traditionally been viewed as a route for civil redress. Across these three jurisdictions, there are a spectrum of rights afforded to patients. While the United States offers parameters for disclosures that are to be provided to a patient, the realities of retaining counsel and proceeding on a claim that only involves inadequate informed consent are bleak. There is technically a cause of action, but it is unlikely to ever be litigated. This puts the United States in the middle of the spectrum. India represents the jurisdiction that arguably affords the lowest in terms of legal redress for a plaintiff with an inadequate informed consent claim. On the opposite side lies Israel, where a violation of a patient's right to autonomy is its own cause of action, and successful plaintiffs may recover non-pecuniary damages.

However, even in a jurisdiction like Israel, where a violation of informed consent provides a plaintiff with a strong cause of action, the legal path seems disappointing. If the purpose behind providing a legal remedy for inadequate disclosures to a patient is to *promote* adequate disclosures, to ensure that physicians are meeting their duty to patients, and to show deference to patient autonomy, then the tort system does not appear to be fulfilling that purpose in any of the jurisdictions analyzed above.

B. Recommendations for Improving Informed Consent

Making the transition towards obtaining better, more thorough informed consent from patients is achievable. This transition starts with improved communication between physicians and patients, and better education for patients about the ins and outs of a proposed treatment. In some countries, the use of technology-assisted education during the time a patient spends in a physician's waiting room would be an ideal bridge for imparting necessary information. This practice has already proven successful in limited studies.¹⁷⁰

In 2012, Wellik and Attwood reported results from a study conducted with the Mayo Clinic wherein patients and their family members were given iPad-like devices loaded with educational materials relevant to their condition and treatment to review while waiting for their appointment.¹⁷¹ Patients overwhelmingly reported having excellent experiences using the devices.¹⁷² During this study, the devices were primarily used as a tool to help patients meditate or reduce their anxiety levels during the time they spent in the waiting room.¹⁷³ However, at the conclusion of the study, researchers were also very optimistic about the future clinical applications such as increasing medical information available to patients.¹⁷⁴

The San Bernardino Medical Group began making tablets available to patients in the waiting room to empower and educate them about their diabetes risk.¹⁷⁵ Patients can take a prediabetes risk assessment using the tablet, and hopefully use the assessment results to create an open dialogue with their physician about lowering their risk.¹⁷⁶ Patients have responded positively, and the group administrators feel the tablets are creating teachable moments out of what used to be wasted time.¹⁷⁷ The tablets were manufactured by Outcome Health¹⁷⁸

¹⁷⁰ Attwood, *infra* note 171.

¹⁷¹ See generally Carol Ann Attwood & Kay E. Wellik, *A Chance to Wait is a Chance to Educate: Exploring Virtual Technology for the Delivery of Patient Health and Wellness Information at Mayo Clinic in Arizona*, 12 J. HOSP. LIBRARIANSHIP 317 (discussing the issues surrounding the choice and utilization of virtual technology for patients and family members as they wait for appointments and procedures).

¹⁷² *Id.* at 325–26.

¹⁷³ *Id.*

¹⁷⁴ *Id.*

¹⁷⁵ Sara Berg, *Tablets Entice Clinic's Patients to Discover Their Diabetes Risk*, AMA WIRE (Aug. 16, 2017), <https://wire.ama-assn.org/delivering-care/tablets-entice-clinic-s-patients-discover-their-diabetes-risk>.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ *Solutions Information and Intelligence to Inspire Positive Patient Outcomes*, OUTCOME HEALTH (last visited Feb. 28, 2018) <https://www.outcomehealth.com/solutions/> [<https://web.archive.org/web/20180214121733/https://www.outcomehealth.com/solutions/>].

which has created a range of digital products designed to engage patients with “educational health content.”¹⁷⁹

There is already some preliminary data that suggests using technology to educate pre-operative patients has benefits.¹⁸⁰ In a small, randomized controlled study, orthopedic surgical patients were given access to a twenty-minute web-based tutorial covering “relevant anatomy, pathology, and general perioperative instructions” plus standard preoperative counseling for their procedure.¹⁸¹ The control group received only standard preoperative counseling.¹⁸² Preoperatively, the group that received the additional web-based tutorial reported feeling significantly more informed about the surgery; they more clearly understood the risks, benefits, and alternatives of the surgery; and they felt more informed about the initial recovery phase compared with the control group.¹⁸³ Not only did the intervention group report feeling more informed, but they were also significantly more likely to correctly answer questions about the surgical details they learned preoperatively at their first postoperative visit.¹⁸⁴ Finally, patients in the intervention group expressed high levels of satisfaction with the web tutorial itself, finding it useful and worth their time without being burdensome.¹⁸⁵

As a practical example of how this method of digital communication could be used to improve the quality of informed consent, consider this mode of information dissemination in the context of a maternity patient. The field of maternity care is particularly well-suited to the implementation of such education because of the nature of pregnancy being a relatively long-lasting condition that follows a fairly predictable course of events. Additionally, the number of office visits typical of routine prenatal care allows for many interactions with such a digital interface, which would ensure adequate time for patients to receive all necessary information and have time for follow-up questions with their physician.

Information available through a digital interface could include physiological changes during pregnancy, thorough information about procedures and tests done during the prenatal period, risks and benefits to common labor and delivery interventions and medications, and even postpartum information which could be disseminated after delivery and before hospital discharge. To accommodate patients who are hearing or visually impaired, or who are not primarily English-speaking, the delivery methods on the device itself should be

¹⁷⁹ *Solutions Information and Intelligence to Inspire Positive Patient Outcomes*, *supra* note 178.

¹⁸⁰ See Bob Yin et al., *Web-Based Education Prior to Knee Arthroscopy Enhances Informed Consent and Patient Knowledge Recall: A Prospective, Randomized Controlled Study*, 97 J. BONE & JOINT SURGERY 964, 964 (2015).

¹⁸¹ Yin et al., *supra* note 180, at 966.

¹⁸² *Id.* at 965.

¹⁸³ *Id.* at 970.

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

comprised of an audio and visual component, and have the option of changing the available language.

There are other aspects of this proposal that are important to consider as well. The costs associated with private prenatal education classes such as Bradley Method classes or Lamaze classes creates a barrier to access for expectant patients who do not have the resources to pay for them. Creating a system of patient education that is consistent, thorough, and available to all patients during the time that they would already be spending waiting for their appointment eliminates this barrier, and creates a more informed experience for all expectant women.

Finally, this solution both closely resembles the shared decision-making model of communication and moves much closer to “consent as a process” rather than “consent as an event.”¹⁸⁶ Engaging maternity patients in this way creates multiple points of contact and has the potential to create more meaningful conversations between patients and providers about their healthcare preferences. While this digital solution may not be a viable option for more impoverished countries, it is a simple yet elegant first step towards increasing the quality of consent processes in places where it *can* be implemented. Perhaps if our fictional patient Sara had access to such a device during her pregnancy, she and Dr. A could have discussed her labor preferences well in advance and avoided the problematic communication and consent issues altogether.

¹⁸⁶ See *supra* Part IV; see generally BERG ET AL., *supra* note 7.

