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History of Informed Consent

The informed consent process that we have today is born through the medicolegal affairs of the twentieth century. While most of us can recall the dictum of “primum non nocere” or above all first do no harm, most physicians would probably be astonished to know that Hippocratic teaching also includes provisions from withholding the necessary details of treatment from the patient, “concealing most things from the patient ... revealing nothing of the patient’s future or present condition” [1, 2]. This recalls the time paternalism was the dominant model of practicing medicine whereby physicians knew best. Early medicine often depended on withholding information from patients. Treatment prior to the turn of the nineteenth century was based on anecdotal and sometimes even baseless evidence. It was not until that late twentieth century that evidence-based medicine was conceived and became popularized [3, 4]. As treatment options and knowledge flourished with the scientific method

and rigorous study design, our model for healthcare delivery has also evolved into one of shared decision making. Shared decision making though is not to be confused with overwhelming patients with information and then letting them choose among the myriad options [2]. After all, patients depend on physicians to be their fiduciary in such matters to guide them through treatment options. To that regard, the informed consent process has evolved in regards to what a physician is expected to disclose.

Unfortunately, the topic of informed consent cannot be broached without referring to the medicolegal affairs that have framed the discussion. Multiple landmark cases have molded what constitutes our modern day informed consent. The three most discussed cases are *Schloendorff v. The Society of New York Hospital* (1914), *Salgo v. Leland Stanford Jr. University Board of Trustees* (1957), and *Canterbury v. Spence* (1972). In the case of Mary Schloendorff, the patient consented to an “ether exam” but subsequently underwent a hysterectomy for a fibroid tumor. The patient sued the hospital because she had not consented to surgery. The defendant’s claim was that the surgery was done on part of beneficence of the patient [5]. Judge Cardozo’s opinion on the case stated “Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent, commits an assault, for

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which he is liable in damages” [6]. The decision ruled in favor of the defendant (the hospital) not being liable for the negligence of its physicians who were independent contractors of the hospital. More importantly, patient autonomy was reaffirmed and most of us are familiar with lack of consent equaling assault and battery.

The Salgo case involved the use of sodium urokon dye for an aortogram with the complication of permanent paralysis afterward. Although a rare complication inherent with the procedure, it was not disclosed prior. Justice Bray wrote “that the patient’s mental and emotional condition is important and in certain cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent” [7]. Katz points out the contradiction within this legal statement of discretion and full disclosure [2]. Indeed, this first mentioning of informed consent was born of the idea that a physician be required to fully disclose the discretionary risks to a patient for a certain procedure. Given this apparent contradiction, it is little wonder why we have so many models of informed consent.

Lastly, in *Canterbury v. Spence*, the “reasonable patient” model of disclosure was born. The plaintiff underwent spine surgery for a ruptured disc with postoperative disability with mobility, urinary incontinence, and bowel problems [8].

It was alleged that the neurosurgeon did not mention the small risk of serious disability. In this regard, the physician should discuss and disclose information based on what a reasonable person would need to know in order to make an informed decision. This contrasts the “professional model” in which a physician should discuss and disclose information based on what other colleagues would disclose in similar circumstances (Table 2.1) [5, 9].

Although these and many other legal cases highlight the need for good documentation, informed consent is not only based on legal safeguards but also ethical principle. Childers and colleagues suggest three main components for ethical informed consent consisting of disclosure, patient understanding, and patient decision making. Disclosure encompasses the patient and physician discussion regarding the details of a treatment or procedure, the indicated need, and also the attendant risks [9]. As discussed earlier, several models of disclosing risk to a patient exist from the professional model to the reasonable model and some amalgam in between. Patient understanding is gauged by the physician and through communication to assess comprehension [10, 11]. Lastly, patient decision making encompasses shared decision making and incorporating the capacity of the patient to make decisions along with their values and preferences [9]. Indeed, the Declaration of Helsinki and the

Table 2.1 Models of informed consent

Model	Definition and problems
Professional model	Disclosure and discussion based on what other physicians would disclose in similar circumstances
	Problem: Promotes generalizations and diminishes importance of individual patient values and interests
Reasonable model	Disclosure and discussion based on what a reasonable patient would want to know
	Problem: What is reasonable to one patient may be unreasonable to the next
Subjective model	Disclosure and discussion based solely on specific interests, values, and life plan of patient
	Problem: Difficult to know every important detail of patient’s life; cumbersome to implement consistently
Balanced model: reasonable and subjective	Disclosure and discussion based on the most important and relevant interests, values, and goals of the patient, as identified by both patient and physician

Used with permission of Elsevier from Childers R, Lipsett PA, Pawlik TM. Informed consent and the surgeon. *Journal of the American College of Surgeons*. Apr 2009;208(4):627–634

Nuremburg Trials demonstrate that informed consent is an ethical standard in allowing patients with capacity to make informed decisions about their own care instead of having treatments imposed upon them. This capacity to give consent is based on the ethical principle of patient autonomy. While physicians may scoff at the idea that patients know how best to be autonomous in their decisions, we have an obligation to be open about the risks, benefits, and alternatives of a procedure and guide them in their decision making process [12–14]. At the heart of shared decision making, physicians serve as facilitators of care who disclose information about treatment options but take into account their patient's preferences to help them come to a conclusion. The decision algorithm for pelvic organ prolapse surgery illustrates this concept. Although quite a prevalent condition, the majority of women with prolapse are not symptomatic [15]. Therefore for a symptomatic patient, no single treatment option serves to be the "right one." Instead the female pelvic medicine reconstructive surgeon elicits a history to further elucidate her preferences as to whether a reconstructive versus obliterative surgery might serve her better. And again (based on what the patient's beliefs and preferences are), the reconstructive treatment algorithm further branches out into uterine sparing versus nonuterine sparing and discusses different surgical approaches. Gone are the days of paternalistic surgeon privilege when a one-size-fit-all approach was administered to every patient without any input. This evolution reflects the myriad surgical options we have and also the evidence that one surgical approach is not necessarily superior to another.

Informed Consent in FPMRS

Given the different treatment options for disease processes in female pelvic medicine and reconstructive surgery, it is important for the physician to foster a relationship with the patient. When surgical treatment options are presented, this decision is impacted by the physician and patient relationship. Multiple papers have evaluated the role of the physician's relationship on impacting

patient care [16–18]. Nowhere is that more true than during procedures that effect quality of life. With these elective procedures, it is important that communication be transparent and deliberate [10]. Tamblyn and colleagues found a significant correlation between low clinical skills examination scores (based on physician communication) and prediction of likely complaints against physicians in Ontario and Quebec [18]. The difficulty in establishing this relationship and communicating effectively manifests in today's medical environment. Quality patient encounters can be hampered by time constraints of the modern doctor's visit. But, we should consider that given the time to talk, most patients speak for 2 min or less while most physicians interrupt within the first 22 s [19, 20]! While quality of care can be determined by patient-driven opinion-dominated metrics, it becomes increasingly more important for the physician to communicate effectively during the limited time with the patient. Studies have demonstrated that patients respond positively to the doctor who addresses their questions and needs [21–24]. Simple portions of the interview such as allowing the patient uninterrupted time to address their concerns, asking for additional questions, and demonstrating empathy improve the physician–patient relationship. All of this trust built during the relationship culminates in the shared formulation of a treatment plan. Often the treatment plan involves shared decision making on a therapeutic intervention. Intervention takes many forms in female pelvic medicine and reconstructive surgery. A prime example of this is the treatment of overactive bladder. Surgery is just one option among many including behavioral modification and medications. Often, education and behavioral modification are all that are needed to make a meaningful impact in one's quality of life. Discussion with a patient regarding caffeine intake reduction and fluid intake modification can make a therapeutic difference without surgical intervention. Regardless of the treatment plan, shared decision making between patient and physician is paramount. This involves education regarding the diagnosis, treatment options including the option of no treatment, open dialog between the physician and patient,

and lastly mutual decision making on the treatment option that should be pursued. Numerous studies have demonstrated that information presented in multiple modalities can serve to enhance the patient's knowledge and satisfaction with the shared decision-making experience [25]. Long gone are the paternalistic doctoring models where only one decision was the correct decision. Today's medicine involves taking into account patient's and family's preferences and wishes. Part of the difficulty with informed consent is based on how much risk to divulge to the patient. There is a fine line between giving enough information so the patient can make an informed decision versus overburdening a patient with superfluous details. Already presented with the *Canterbury v. Spence* case was the model of the reasonable patient. But rather than placing all decisions in a rigid matrix, a combined approach taking into account patient preferences and values in addition to what a reasonable patient would want to know is probably the best method of informed consent. In this regard, the surgeon would discuss the risks for a surgery that a reasonable patient would want to know and also include any additional risks, however low risk they may be, that may be in accordance with a patient's values. Framed in this context of overactive bladder treatment, a patient may best be served by sacral neuromodulation for overactive bladder if the risk of urinary retention with another treatment is unacceptable to the patient. This model can only be utilized if a physician has spent time elucidating the patient's preferences and goals through building the physician-patient relationship.

Another difficulty regarding informed consent is the realization that this process happens before any paperwork is signed for surgery. Informed consent as it applies to surgical procedures is typically the piece of paper or document in the medical record that has the patient's signature. In reality, the signature documents that the discussion took place prior between the physician and patient. *It does not replace this discussion.* And it is during this discussion that the physician has the ability to impact the patient's perception of any outcome of a surgery. The informed consent

should take place in a non-hurried setting where the physician has a chance to explain the procedure, the patient has the chance to ask questions, and the physician has a chance to answer these questions and check for comprehension and understanding [11]. The documentation itself should not be trivialized because it serves as an objective part of the medical record. Components that should be included in any documentation include a description of the procedure in understandable terms, details of the risks/benefits documentation that the risks/benefits and alternatives were discussed including the option of no surgical intervention, and then an attestation that the patient had a chance to ask questions [9, 10]. With most shared decision in FPMRS cases, we enjoy the luxury of discussing treatment options in our office without emergent need for an operation. For more complex decisions regarding surgical treatment options, it would serve us well to educate our patient so that they can be an integral part of the shared decision making process and be diligent about all steps of the informed consent process. An example of this can be found in subtleties of informed consent in any procedure using synthetic mesh.

Informed Consent and Patient Perception in the Realm of Mesh

Patients need to be able to comprehend the treatment options at hand and informed consent needs the understanding of both parties to proceed. The physician should use empathy to try and understand the patient's preferences while the patient needs to be able to understand the risks/benefits and alternatives to any procedure. Unfortunately with all the litigation surrounding mesh-based prolapse repair, patient education between fact and fiction can often times be difficult. Multiple studies have demonstrated that patients are misinformed regarding the use of synthetic mesh in prolapse repair and also the litigation involved using synthetic mesh. Unfortunately, patients also are deriving most of their information from sources other than their physicians demonstrating a need for increased patient education [26, 27].

Pelvic organ prolapse and incontinence are difficult concepts for the patient to clearly understand and recall at baseline [28]. Given the difficulty in understanding this subject, jargon should be kept at a minimum. Language should not be condescending and risks and benefits of a procedure explained in a simple and concise manner. Regarding procedures, the more information afforded to the patient the better. Given the misconception about synthetic mesh, informational tools such as FAQs from AUGS and SUFU can be used for further patient education. The joint FAQ on mesh mid-urethral slings for stress urinary incontinence highlights the important role of professional societies to also provide information to help patients make informed decisions [29]. These tools serve as an adjunct to informed consent and are not meant to replace discussion between physician and patient but rather to reinforce patient knowledge. Patients are then empowered to make an informed decision regarding their care. The International Urogynecological Association published a consensus paper with a sample consent for use with transvaginal prolapse surgery repair [10]. Again it should be noted that such an extensive consent serves a twofold purpose, as evidence that a shared decision-making process took place and that informed consent was obtained. Studies have demonstrated that patients better understand informed consent when given information in multiple modalities [25, 30]. This agrees with principles in learning and teaching that not only auditory processing but also visual processing matters as well to enhance comprehension [31]. Interestingly, it is assumed that patients will be able to read their after-visit summary for further information and instructions regarding a procedure. But it should be noted that patient's preferences for receiving information should be ascertained prior to ending a visit because some patients may be illiterate and too ashamed to mention this when receiving their after-visit summary [28, 32, 33]. While many of these considerations are assumed during an office visit or during a process such as informed consent, all of these must be considered to ensure that the patient has all the tools available to be involved in the shared decision making process.

Conclusion

Informed consent refers to the process by which the physician and patient agree to a plan formulated concerning the patient's care. There are two key components to informed consent—one, that the physician inform and disclose information to the patient and two, that the patient consents to this formulated plan of care. The heart of informed consent lies within the shared decision making between the physician and the patient. Informed consent has both a medicolegal and ethical basis. In female pelvic medicine and reconstructive surgery, shared decision making should take place between the physician and patient with clear communication and established rapport to come to a decision that is both acceptable to everyone in regards to treatment outcomes and also patient's preferences. To that extent, multiple modalities provided by professional societies should be used such as published FAQ's and other resources. These can be used to clearly communicate and inform patients so that shared decision making becomes the cornerstone of any treatment plan and expectations regarding benefits and complications are clearly understood.

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