The Age of Informed Consent

The Age of Informed Consent:

A European History

Edited by

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CHAPTER I

INTRODUCTION

SORIN HOSTIUC

Nowadays, informed consent (IC) is considered one of the most important practical concepts in bioethics and is essential for respecting the autonomy of patients in their relationships with healthcare professionals. In biomedical sciences, informed consent is unarguably the most important type of consent, but it is not the only one; the most important varieties are summarized in the Table below.

Table 1. Types of consent in healthcare

Types of consent	Description
Informed (or autonomy based)	Consent is obtained voluntarily, only after the patient/ subject received and understood relevant information. The patient/subject must have civil competence to validate the consent.
Implied	Consent is obtained implicitly, through particular actions/inactions, behaviors, or situations. For example, when a patient comes to a medical consultation, the consent for it is considered as implied
Presumed	Unless the patient/subject has explicitly refused a particular medical procedure, it can be performed without an explicit consent. Typically associated with do not resuscitate procedures or organ transplantation.
Medical (or beneficence based)	The main drive behind it is the wish of the physician to aid the patient and not to respect the autonomy. It is a precursor of the informed consent in many cultures.
Assent	Has the same characteristics of informed consent, but without the need to be validated from a legal point of view. It is often used in pediatrics.

Many authors have argued that the concept of informed consent, as we know it today, only appeared in the middle of the 20th century, usually linking it with either the Nuremberg Code or the Salgo case, which are both analyzed in the next chapter. For example, Robert Veatch stated that:

> *Although the nineteenth century saw no hint of a rule or practice of informed consent in clinical medicine, consent procedures were not entirely absent (…) However, the consents obtained do not appear to have been meaningful by contemporary standards of informed consent because they had little to do with the patient's right to decide after being informed. Before the 1950s, practices of obtaining consent for surgery were pragmatic responses to a combination of concerns about medical reputation, malpractice suits, and practicality in medical institutions. It is physically difficult and interpersonally awkward to perform surgery on a patient without obtaining the patient's permission. Such practices of obtaining permission, however, did not constitute practices of obtaining informed consent, although they did provide a modest nineteenth-century grounding for this twentieth-century concept*[1].

Faden and Beauchamp indicated that "Prior to this period (late 1950s and early 1960s), we have not been able to locate a single substantial discussion in the medical literature of consent and patient authorization. For example, from 1930 to 1956 we were able to find only nine articles published on issues of consent in the American medical literature"[2]. B. Rich specified that, before the Salgo case, consent-related malpractice claims in the United States debated whether a proper consent was obtained, and not whether the information given to the patient was appropriate, therefore suggesting that the consent obtained at the time lacked a fundamental characteristic, namely, information, which is a mandatory precondition, based on current standards:

> *…while some of the early court opinions employ language suggesting that a patient's consent to treatment should be based upon the disclosure of relevant information, an analysis of the facts of these cases indicates that each was an instance in which there was no consent at all, informed or otherwise, to the treatment that was administered. Over fifty years were to pass before a reported case would address the issue of a physician's*

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[1] Robert M. Veatch, *Medical Ethics* (Jones and Bartlett Publishers Inc, 1996), 187; see also Robert Baker and Laurence B McCullough, *The Cambridge World History of Medical Ethics* (Cambridge; New York: Cambridge University Press, 2009), 4.

[2] Ruth R. Faden, Tom L. Beauchamp, and Nancy M. P. King, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986), 86.

responsibility to disclose any detailed information about the procedure for which the patient's consent is being sought[3].

Therefore, the focus of consent was on authorization (of a contractual relationship between the physician and the patient), and not on obtaining a properly informed decision from a patient able to make autonomous choices. According to Faden and Beauchamp, when looking at historical evidence on consent, it appears to be informed (and therefore complies with current definitions of informed consent) if these three conditions are simultaneously met at any given time: (1) the patient agrees to a medical intervention after properly understanding the relevant information; (2) consent is not controlled by external influences able to alter the outcome; and (3) consent involves an intention to give permission for an intervention[4]. This interpretation, which may work in certain conditions for a US-centric concept of informed consent, is of limited use in other parts of the world. For example, in many European countries, medical decision-making has always been a "family matter." Patient autonomy has often been subject to the moral obligation of aiding a family member, and physicians have had to respect this aspect, as otherwise the patients and their families would lose trust in them, as is discussed in later chapters. Even nowadays, many patients in Romania see physicians who ask them to make choices as weak, or untrustworthy, and unable to identify the best course of action for their condition. For this reason, one of the major issues physicians have to confront is how to identify what type of physician-patient relationship is preferred by a certain patient, and depending on the preference identified, to shift between an informative and a more paternalistic approach (with numerous in-between variations). Patient autonomy is still respected, as patients do express their wishes, the information is available, and understanding of the relevant information is still a pre-requirement of any medical intervention, but an external control is often seen as desirable by patients (provided either by physicians, in a paternalistic physician-patient relationship, or by the family, who decides the best course as a unit). As is indicated in chapters concerning the evolution of informed consent in Croatia and France, shared decision-making is still seen as a norm in medical practice, and a strongly informative model has not been completely accepted in everyday medical

[3] Ben A Rich, *Strange Bedfellows: How Medical Jurisprudence Has Influenced Medical Ethics and Medical Practice* (Springer Science & Business Media, 2001), 53.

[4] Ruth R. Faden, Tom L. Beauchamp, and Nancy M. P. King, *A History and Theory of Informed Consent* (Oxford: Oxford University Press, 1986), 54.

practice. Does this mean that in these countries there is no proper informed consent but rather only medical consent? Should informed consent be seen as a "one size fits all," or as a culture-centric concept? These are just some of the questions we attempt to address in this book.

Therefore, the purpose of this book is to reveal how medical consent has been conceptualized in various parts of continental Europe and to identify whether, and from what point in time, it is possible to discuss informed consent as a clearly identifiable concept in this part of the world. We do not intend to perform an exhaustive analysis, but rather to highlight relevant evidence in relation to our questions, which could be used by other researchers to deepen this field of study. As far as possible, we have relied on quotations taken from primary sources in support of our views (left in their original language if detailed in footnotes, and translated in the main text). We also present some landmark events in the evolution of informed consent in the US and the UK, as most works analyzing the history of informed consent refer to these events and they provide readers with references points.

Before discussing the evolution of informed consent in certain European countries, one could ask whether it is possible to discuss informed consent before this term was coined. To address this question, two further questions require attention: (1) should a universalist or a pluralist approach to informed consent be used, and (2) what theoretical model for the history of informed consent should be used?

Should a Pluralist or a Universalist approach to Informed Consent be used?

According to Levine, ethical universalists believe there is a universal set of ethical principles governing all human beings[5], regardless of their social, cultural, regional, and educational status. Noam Chomsky defined the golden rule for ethical universalism as follows: "If an action is right (or wrong) for others, it is right (or wrong) for us. Those who do not rise to the minimal moral level of applying to themselves the standards they apply to others—more stringent ones, in fact—plainly cannot be taken seriously when they speak of appropriateness of response; or of right and

[5] Robert J Levine, "International Codes and Guidelines for Research Ethics: A Critical Appraisal," in *The Ethics of Research Involving Human Subjects: Facing the 21st Century*, ed. Harold Y Vanderpool (Frederick, MD: University Publishing Group, 1996), 237-49.

wrong, good and evil"[6]. Ethical principles are viewed as pre-existent, applicable everywhere and for everyone, and the duty of ethicists is to reveal them. The pluralist approach considers that: "All ethical principles are developed in the course of discussion held within particular cultures and that these discussions necessarily reflect the unique histories and other circumstances of particular cultures"[7]. According to this approach, ethical principles are invented, not discovered, and the purpose of ethicists is to organize them into a coherent framework. The most influential codes of ethics, including the Nuremberg Code and the Oviedo Convention, are based on the universalist approach. For example, in the preamble of the Nuremberg Code, it is stated: "All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts." In this formulation, these basic principles cannot be other than universal[8]. Other guidelines for research ethics, however, have been built on a more pluralist approach. Levine, in discussing a commentary on guideline 15 from the Council for International Organizations of Medical Science (CIOMS) Guidelines, which states "Ethical review in the external sponsoring country may be limited to ensuring compliance with broadly stated ethical standards, on the understanding that ethical committees in the host country will have greater competence in reviewing the detailed plans for compliance"[9] argued that this demonstrated a willingness to particularize ethical norms based on local cultural traits in line with a pluralist approach, which facilitates acceptance of the CIOMS Guidelines worldwide.

If a universalist approach were to be adopted, it could be considered that informed consent, as a principle based on the autonomy of the patient, clearly precedes the Nuremberg Code and/or the Salgo case; even if not clearly defined as a concept, some basic elements of informed consent should be identifiable on a closer scrutiny of medical studies before World War II. Subsequently, it would not be possible to discuss the origin of informed consent but rather only its emerging manifestation as a distinct concept. If a pluralist approach were to be adopted, then it could be considered that informed consent might have originated when enough data concerning it had crystalized, such as, for example, occurred with the

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[6] Noam Chomsky, "Terror and Just Response," *Terrorism and International Justice* (2003): 1-13.

[7] Levine, 237-49.

[8] Michael A Grodin, "Historical Origins of the Nuremberg Code," in *The Nazi Doctors and the Nuremberg Code*, ed. George J. Utley and Edward R. Annas (USA: Oxford University Press, 1992), 121-44.

[9] Council for International Organizations of Medical Science (CIOMS) Guidelines

publication of the Nuremberg Code or with the Salgo case. However, if a pluralist approach were used to understand the development of informed consent, then it appears that a specific set of guidelines might not be applicable worldwide. For example, Levine contended that the Nuremberg Code was an American creation, with fundamental principles derived from American culture[10]. This background resulted in a series of limitations of the Code that made it almost unusable in clinical practice (see Emmanuel[11] or Hostiuc[12] for a detailed discussion of these limitations). Therefore, for a concept such as informed consent to emerge, various sources, events, and people would have to be involved and combined at a specific moment in time, which might have been the moment of the Nuremberg trials in respect of informed consent in clinical research. The emergence of a concept involves a process; therefore, preexistent elements should be identifiable. If certain relevant elements are recognized before the advent of a certain concept, can these elements be described using the name of that concept? Could informed consent be a topic of medical ethics before it appeared as a term, with a proper definition? To answer this question, it is necessary to look to the evolution of another very closely related concept, that of bioethics.

Most authors consider the birth of bioethics to be a recent event, apparently connected with the use of this term by von Rensselaer Potter at the beginning of the 1970s. Reich, for examples, stated that:

> *Extensive historical sleuthing reveals that the word "bioethics" and the field of study it names experienced, in 1970/1971, a "bilocated birth" in Madison, Wisconsin, and in Washington, D.C. Van Rensselaer Potter, at the University of Wisconsin first coined the term; and André Hellegers, at Georgetown University, at the very least, latched onto the already-existing word "bioethics" and first used it in an institutional way to designate the focused area of inquiry that became an academic field of learning and a movement regarding public policy and the life sciences"*[13].

In a similar fashion, Martensen stated that:

> *According to Sargent Shriver, he invented the word "bioethics" in his own Bethesda, Maryland, living room one night in 1970.(...)That evening he and*

[10] Levine, 237-49.

[11] Ezekiel J Emanuel et al., *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press, 2011), 136-41.

[12] Sorin Hostiuc, *Informed Consent [Consimțământul Informat]* (Cluj-Napoca: Casa Cărții de Știință, 2014).

[13] Warren Thomas Reich, "The Word" Bioethics": Its Birth and the Legacies of Those Who Shaped It," *Kennedy Institute of Ethics Journal* 4, no. 4 (1994): 17-18.

his wife, Eunice Kennedy Shriver, met with physician Andrée Hellegers, the president of Georgetown University and a Jesuit philosopher, and others to discuss Kennedy family sponsorship of an institute for the application of moral philosophy to concrete medical dilemmas. Now bioethics is thirty years old, the traditional span of a generation, and has reached an anniversary that invites reflection[14].

However, the word "bioethics" was coined half a century earlier, by Fritz Jahr[15]. Despite his work being largely unknown until recently[16], there were other, related disciplines, such as medical ethics, or deontology, which contained many aspects appertaining to the current concept of bioethics, including for example the morality of animal research, medical research, and ecological ethics[17], marking bioethics more as a renaming of aspects within older disciplines, rather than a new discipline per se.

Baker and McCullough, in a chapter discussing the history of medical ethics, suggested that there are three potential approaches to this topic[18]:

- A presentist construction of medical ethics—historians would assume that, because today we have the concept, people from other places and times also had a similar concept[19].
- A pragmatic construction of medical ethics—to emphasize certain elements, historians and ethicists would use historical narratives. This approach allows bioethicists and medical ethicists to "frame the past to reflect their approach to the future"[20], but has, as a principal disadvantage, a substantial risk of overlap with the presentist approach (if a thing is bad now, it was bad before).
- A traditionalist approach—the history of medicine overlaps with the history of medical ethics itself; for example, Hippocrates wrote not only medical treatises, but also his Oath. This approach is used

[14] Robert Martensen, "The History of Bioethics: An Essay Review," *Journal of the History of Medicine and Allied Sciences* 56, no. 2 (2001).
[15] Fritz Jahr, "Bioethik," *Kosmos* 24, no. 1 (1927).
[16] Amir Muzur and Hans-Martin Sass, *1926-2016 Fritz Jahr's Bioethics*, vol. 33 (LIT Verlag Münster, 2017).
[17] Aldo Leopold, "The Conservation Ethic," *Journal of Forestry* 31, no. 6 (1933).
[18] Baker and McCullough, 5-8.
[19] Ibid.
[20] Ibid.

> to legitimate various issues "by wrapping it in the mantle of ancient authority"[21].

Most medical historians today use either a pragmatic construction (mostly Anglo-Saxon countries) or a traditionalist approach (often those from continental Europe, but also Latin America). From our analysis of many historical works regarding the evolution of the concept of informed consent, we consider that these works have rarely adopted a presentist approach, with the primary assumption of these works being that, because a certain concept (in this case informed consent) does not fulfill all the major requirements expected today, everything that was written or undertaken in clinical and research practice beforehand cannot therefore be encompassed in that concept. If we were to apply a similar approach to another subject, the discovery of anesthesia might very well be associated with the introduction of isoflurane in clinical practice as an inhalational anesthetic; therefore, everything used beforehand was not anesthesia but something else. Another example could be the introduction of laparoscopy in surgery; everything that was done in the relevant area beforehand was not surgery, but only a primitive method through which surgeons tried to cure patients by slicing them open. By using extensive primary source literature, we will show that consent was an intrinsic part of medical practice well before the second half of the 20th century; moreover, although informed consent was not the same as today, this consideration is the equivalent for society in general and for medicine in particular. Informed consent has greatly evolved since its arrival into mainstream bioethics. Consent, as an intrinsic part of the physician-patient relationship, developed over the course of many centuries, and it is not possible to artificially impose a specific moment of origin. Moreover, as discussed in the chapter regarding the history of informed consent in France, the specific term "informed consent" was used decades before the Salgo case.

Early uses of Medical Consent

Dalla-Vorgia et al. suggested that medical consent as a concept began to be used from antiquity, and started their analysis with Plato's dialogue, "Laws," in which he differentiated real (free) doctors from slave-doctors, who treated slaves. While slave-doctors did not provide any information to their patients, this was not the case with free doctors, who sought

[21] Ibid.

information from their patients and the friends of patients and, after gathering the necessary data, informed their patients about the nature of their illness, and only initiated treatment after obtaining their consent[22]. Katz argued a contrary viewpoint, stating that in the Hippocratic tradition there were no discussions regarding the treatment options or the reasoning behind the recommendations of physicians[23]. Regarding Plato's dialogues, Katz stated that "Plato, whose Dialogues give a reasonably complete account of medical practice in classical Greece, did not suggest that the lively interactions among the participants in his Dialogues should become a model for the interactions between physician and patient"[24].

In the British colonies, the earliest roots of medical consent can be found in the 17th century, in one of the first laws regulating health professionals, where it was stated that "no person or persons may be employed … as chirurgeons [surgeons], midwives, physicians or others may presume to set forth or exercise any act contrary to the known approved rule of art… upon or towards the body of any … without the … consent of the patient or patients if they be in mentis compos, much less contrary to such consent"[25].

Before the 19th century in the Ottoman Empire, the legal status of physicians was regulated through instructions deriving from head physicians and official regulations. For example, Sert and Güven analyzed two court rulings from the Ottoman period in which were accusations against physicians for not obtaining the consent of their patients[26]. This led to a practice, even if not clearly regulated, of getting the consent of the patient before performing a high-risk medical procedure. For example, Sayligil and Ozden have recently published a written consent, dated 1524, from Bursa (Ottoman Empire), which states:

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[22] P Dalla-Vorgia et al., "Is Consent in Medicine a Concept Only of Modern Times?" *Journal of Medical Ethics* 27, no. 1 (2001).
[23] Jay Katz, *The Silent World of Doctor and Patient* (JHU Press, 2002), 1-5.
[24] Ibid.
[25] Joseph Meredith Toner, *Contributions to the Annals of Medical Progress and Education in the United States before and During the War of Independence* (Washington 1874), 36.
[26] Gürkan Sert, Tolga Güven, and Şefik Görkey, *Medical Law in Turkey* (Kluwer Law International, 2011), 52.

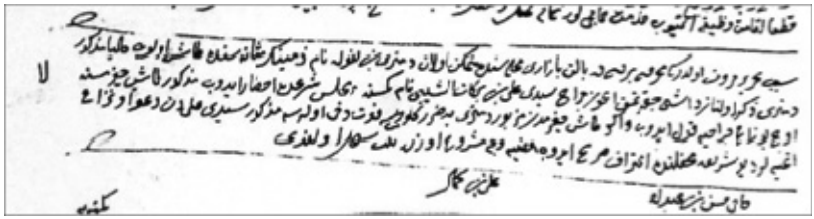

Figure 1 Written consent from 1524, Bursa (from Sayligil et al, CC4 license)

> *This is written to certify that Dimitri bin Nikola, a dhimmi (a non-Muslim living in the Ottoman Empire), resident in the Balıkpazarı neighborhood of the city of Bursa, who has a stone in his bladder, presented with Surgeon Cerrah Seydî Ali bin Berekât es-Seybî to the court hearing to have the stone removed, agreeing in the Sharia court in the presence of the qadi that he would pay 300 akçe (silver coins) for the removal of stone and that Seydi Ali would not be sued if Dimitri is harmed or even loses his life due to the stone removal." Witnesses: Hacı Hasan bin Abdullah Ali bin Kemal (Date: 26 Dhu al-Qi'dah 933)*[27].

This consent implied a strongly contractual relationship between physician and patient, with a clear delineation of the risks assumed by each party. In this case, the patient took upon himself the risks of harm or even death seen as potential complications of the surgery he had agreed to.

Christopoulos et al. analyzed the presence of medical consent in the eastern Mediterranean region during the 17th and 18th centuries, using official documents from 164 surviving registers from the Islamic Court of Candia (Heraklion) that detailed descriptions of interactions between patients and physicians. It was often the case that a physician performed a treatment only after discussing it with the patient and/or the legal guardian. For example:

> *Because, by the will of God, a stone has formed in the bladder of my son Michalis, who is my legal son and is present afore the Council, aged 9 and who suffers from great pains and irritation when urinating, and because the surgeon Themelis is experienced in this treatment, I hired this experienced doctor for a certain period and for a certain lease, in my capacity as parent, to cure my son. He accepted this lease and I ordered that he cut the part where the stone is placed and clean the bladder. If due to the cutting that the surgeon shall conduct (...) my son Michalis should*

[27] Omur Sayligil and Hilmi Ozden, "A Written Consent Form Dating Back to 1524 in Bursa Ser'iye (Sharia Court) Records and a Proposal of a New Start Date for Consent Forms," *Annals of Saudi Medicine* 34, no. 5 (2013).

die, then I discharge now, in the capacity that I mentioned above, the obligation of the surgeon mentioned herein from the depositing of the diyet and declare that I will not have any disputes with him. The above was ratified in accordance with the divine law and this deed — registered today, 11 April 1756[28].

From this text, three clear observations can be made: (1) the physician (surgeon)-patient relationship was strongly contractual, involving here a case in which the consent of both parties had to be obtained before the enforcement of the contract; (2) some information was obviously exchanged during this relationship, proven by the fact that the parent knew the potential risks facing his son (including the risk of dying); and (3) consent for the medical procedure was needed before being performed by the surgeon.

From the late 19th century and into the 20th century, we found examples of consent in many countries that are quite similar in form to those used today in clinical practice. As one example, we present a consent form, signed by a patient for a thyroid transplant, which was published in *Medicinskoe Obozrenie* [Medical Review], a Russian medical journal, in 1917:

I, the undersigned E. R., by myself, without any external influences, offered a piece of my thyroid gland for transplantation. The piece would be of the size required for successful transplantation (approximately up to one eighth of the gland's volume). I have had all the details explained to me and I am aware of all the risks I am subject to, i.e.: (1) as a result of an unsuccessful operation life-threatening bleeding can occur; (2) suppuration of neck and even blood contamination can follow, which can result even in death. I was told that the effect of the operation on the human health is not yet known, because this operation is very rarely performed, and that in the books where it is described it is not stated how the people from whom pieces of thyroid gland were taken felt themselves, but experiments on animals prove that one can remove up to two-thirds of the thyroid gland without doing any harm to the animal, and that because with respect to the thyroid animals and human beings are similar, these conclusions are probably applicable to humans as well; and indeed, when the tumors of thyroids are removed, it can be enough to preserve a very small portion of it so that the person can continue living without experiencing troubles related to the absence of the thyroid gland. I am also aware how a shortage of thyroid gland affects the human. Then I was told

[28] Platon Christopoulos et al., "Aspects of Informed Consent in Medical Practice in the Eastern Mediterranean Region During the 17th and 18th Centuries," *World Journal of Surgery* 31, no. 8 (2007). With permission of Springer

that although I will have analgesic medicine injected under the skin for pain relief, I will possibly feel some pain during the surgery and afterwards. And finally, it was explained to me, that in the case of successful operation or especially if the wound suppurates I will have a scar for life on my neck about 7.5- 10 cm long. And, despite all the facts mentioned above, I agree to the surgery, and whatever happens, I will never have any claims either against the doctors who will perform the surgery, or the patient who will receive my thyroid gland. I am signing this paper in the presence of doctors B. V. Dmitriev, E. K. Vinakurova, M. P. Alexeev and the nurse E. V. Shevchenko (signature); we witnessed the reading and signing of this paper and hereby certify that E. P. is an adult and mentally capacitated person (signatures of doctors and nurse).[29]

From this example, it is clear that, at least in some cases, consent forms were employed in clinical practice; moreover, the consent was written after a proper analysis of the intervention and its risks, and the signatory had to be legally competent (an adult) and with decision-making capacity (a mentally capacitated person).

Of course, these examples, as those discussed in following chapters, do not necessarily indicate widespread use of consent in clinical and experimental practice (due to issues arising in seeking to distinguish between confirming adequate criteria for a practice and inadequate evidence per se, as highlighted by Faden and Beauchamp)[30]. It is entirely possible that the examples we provide do not show the most likely scenarios regarding the practical use of consent, and it is entirely possible that most physicians and researchers did not comply with general rules suggested by these examples. However, they allow us to identify some precursors of this concept, present in various contexts, and with increasing frequency from the end of the 19th century. The concept of consent had emerged within the medical discourse; breaches were considered examples of either illegal or unethical behavior; physicians had started to use it (at least some of them) in everyday practice; those involved in medical practices often required consent before starting human experimentation; and legislators had started developing regulations emphasizing its required use in practical circumstances.

[29] Olga I. Kubar and A. G. Asatryan, "Establishment of the Ethical Review System & Ethics Committees in the Region," in *Ethical Review of Biomedical Research in the CIS Countries (Social and Cultural Aspects)* (Sankt-Petersburg: UNESCO, 2007), 77-78.

[30] Faden, Beauchamp, and King, 54.

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CHAPTER II

A SHORT INTRODUCTION TO THE HISTORY OF INFORMED CONSENT IN GREAT BRITAIN AND THE UNITED STATES

SORIN HOSTIUC

While the evolution of the concept of medical and informed consent within certain European countries forms the primary analysis of this book, many features cannot be discussed adequately without referring first to what happened in the US and the UK, as today's concept is largely based on what was developed there.

In the 19th century and the first half of the 20th century, physicians in the US and the UK employed a practice now called "simple" or "medical" consent[1], which had four principal roots, comprising moral[2], medical[3], experimental[4], and legal[5] aspects, often combined within clinical and research practice.

The Moral Roots of Informed Consent

The moral roots of informed consent were principally drawn from the notion of respect for individual choice, a cornerstone of Enlightenment philosophy. John Stuart Mill, for example, considered that no one should deny the liberty of citizens, even for their own benefit, unless the rights of

[1] Thomas Grisso and Paul S. Appelbaum, *Assessing Competence to Consent to Treatment: A Guide for Physicians and Other Health Professionals* (Oxford University Press, 1998), 4.
[2] Ibid., 4
[3] Sorin Hostiuc, *Informed consent [Consimțământul informat]* (Cluj-Napoca: Casa Cărții de Știință, 2014), 5-18.
[4] Ibid.
[5] Grisso and Appelbaum, 4.

others were endangered[6]. John Gregory (1724-1773) and especially Benjamin Rush (1745-1813)[7] considered that physicians had a duty to inform their patients; a duty arising from the conviction that self-determination and happiness aided in patient healing. However, this duty often conflicted with the one to do good, in which case beneficence was considered the more important moral value and patient authorization of the physician to intervene was not mandatory. As John Gregory noted:

> *Curiosity in a patient or his friends to know the nature of the medicines prescribed for him is natural, and therefore not blameable (sic); yet this is a curiosity which is often very improper to gratify. There is a natural propensity in mankind to admire what is covered with the veil of obscurity, and to undervalue whatever is fully and clearly explained to them. A firm belief in the effects of a medicine depends more on the imagination, than on a rational conviction impressed on the understanding; and the imagination is never warmed by any object which is distinctly perceived, nor by any truth obvious to common sense. Few people can be persuaded that a poultice of bread and milk is in many cases as efficacious as one compounded of half a dozen ingredients, to whose names they are strangers; or that a glass of wine is, in most cases where a cordial is wanted, one of the best that can be administered. This want of faith in the effects of simple known remedies, must of necessity occasion a disregard to the prescription, as well as create a low opinion of the physician. Besides, where a patient is made acquainted with the nature of every medicine that is ordered for him, the physician is interrupted in his proceedings by many frivolous difficulties, not to be removed to the satisfaction of one ignorant of medicine. The consequence of this may be to embarrass the physician, and render him irresolute in his practice; particularly in the administration of more powerful remedies*[8].

According to Rush and Gregory, physicians should be inflexible when the disease was severe[9], and their medical decisions should never be questioned[10]. Benjamin Rush also believed that enlightened patients would voluntarily submit their will, regarding medical decisions, to physicians, while unenlightened patients were seen as unable to make medical

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[6] John Stuart Mill, *On Liberty* (London: Electric Book Co, 1999), originally published in 1859.

[7] Benjamin Rush, *Medical Inquiries and Observations*, vol. 2 (Philadelphia: J. Conrad & Co., 1805).

[8] John Gregory and Laurence B. McCullough, "John Gregory's writings on medical ethics and philosophy of medicine," Academic Publishers.

[9] Rush, 2.

[10] *Sixteen Introductory Lectures*, ed. Benjamin Rush (Bradford, Philadelphia 1811).

decisions, and therefore the only viable alternative was for physicians to act as bonus pater familias. He claimed that physicians should "yield to them [the patients] in matters of little consequence, but maintain an inflexible authority over them in matters that are essential to life"[11]. As a practical example, in a letter from 1793, he stated "I have great pleasure in informing you that Dr…. is much better. He was bled five times. After the 3rd bleeding an old patient of Dr…'s went down to Gloucester and begged Mrs… in the most pathetic terms not to consent to his being bled again. Mrs…. acted with firmness and propriety, and submitted to the subsequent bleedings with full confidence of their being proper, tho' advised only by Mr. Coxe"[12].

Thomas Percival, the author of the celebrated "Medical Ethics" (1803), a text that remained the basis of Anglo-Saxon medical ethics for the following 150 years, had a slightly different opinion. According to him, truth-telling was a duty, while beneficence was a virtue. When virtues and duties were divergent, the former always had to prevail[13]. His analysis regarding the need for truth-telling was set out largely in a chapter entitled "A physician should be the minister of hope and comfort to the sick", from which is quoted here a lengthy passage, to show how this subject was viewed both by Percival and by his predecessors. The chapter begins with a letter Percival had received from Thomas Gisborne, an author of works including "An Enquiry into the Duties of Men in the Higher and Middle Classes of Society in Great Britain" and "An Enquiry into the Duties of the Female Sex." In the former work, Gisborne had stated, concerning surgical interventions in hospitals, that: "It may be a salutary, as well as a humane act, in the attending physician, occasionally to assure the patient that everything goes on well, if that declaration can be made with truth"[14]. To this, Percival responded that:

> *Humanity, we admit, and the welfare of the sick man commonly require, that his drooping spirits should be revived by every encouragement and hope, which can honestly be suggested to him. But truth and conscience forbid the physician to cheer him by giving promises, or raising*

[11] Dagobert Runes, *The Selected Writings of Benjamin Rush* (The philosophical library, 1947), 313.
[12] Ibid., 412.
[13] Albert R. Jonsen, *A Short History of Medical Ethics* (Oxford, New York: Oxford University Press, 2000), 58-67.
[14] Thomas Percival, *Medical Ethics. Or, a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons: to Which Is Added an Appendix; Containing a Discourse on Hospital Duties; Also Notes and Illustrations* (Oxford: Hohn Henry Parker, 1803), 157.

expectations, which are known, or intended to be, delusive. The physician may not be bound, unless expressly called upon, invariably to divulge, at any specific time, his opinion concerning the uncertainty or danger of the case; but he is invariably bound never to represent the uncertainty or danger as less than he actually believes it to be; and whenever he conveys, directly or indirectly, to the patient or to his family, any impression to that effect, though he may be misled by mistaken tenderness, he is guilty of positive falsehood. He is at liberty to say little; but let that little be true[15].

Percival regarded truth-telling in healthcare as a binomial construct – "one to the party to whom it is delivered, and another to the individual by whom it is uttered"[16]. Truth-telling in relation to a patient was subject to the principle of beneficence, while in relation to the physician it was subject to virtues such as purity, sincerity, and probity. In situations of conflict, the duty to do good had to prevail:

In the first (duty to the patient, n.n.), it is a relative duty, constituting a branch of justice; and may be properly regulated by the divine rule of equity prescribed by our Saviour, to do unto others, as we would, all circumstances duly weighted they should do unto us. In the second, it is a personal duty, regarding solely the sincerity, the purity, and the probity of the physician himself. To a patient, therefore, perhaps the father of a numerous family, or one whose life is of the highest importance to the community, who makes enquiries which, if faithfully answered, might prove fatal to him, it would be a gross and unfeeling wrong to reveal the truth. His right to it is suspended, and even annihilated, because its beneficial nature being reverse, it would be deeply injurious to himself, to his family, and to the public; and he has the strongest claim, from the trust reposed in his physician, as well as from the common principles of humanity, to be guarded against whatever would be detrimental to him. In such a situation, therefore, the only point at issue is, whether the practitioner shall sacrifice that delicate sense of veracity, which is so ornamental to, and indeed forms a characteristic excellence of the virtuous man, to this claim of professional justice and social duty. Under such a painful conflict of obligations, a wise and good man must be governed by those which are the most imperious; and will therefore generously relinquish every consideration, referable only to himself[17].

Therefore, according the Percival, beneficence should prevail in all instances in which the truth might hurt the patient, such as oncological diseases, emergencies, and terminal afflictions. This approach was

[15] Ibid., 157-58.
[16] Ibid., 165.
[17] Ibid., 165-66.

identifiable in the American Medical Association (AMA) Codes of Ethics until the 1950s. For example, in the 1903 AMA Code, Chapter 1, Section 6, it was stated: "The physician should be a minister of hope and comfort to the sick, since life may be lengthened or shortened not only by act but by the words or manner of the physician, whose solemn duty is to avoid all utterances and actions having a tendency to discourage and depress the patient"[18].

Consent in Clinical Medicine

In the 19th century, obtaining consent in clinical practice was not something unusual, as seen by the process of obtaining consent that was detailed in many books, articles, memos, or personal notes. However, issues were likely to arise when consent could not be obtained or was withheld.

For example, John Erichsen, in a chapter entitled "General considerations on operations" taken from his work "Science and Art of Surgery" (1854), wrote that:

> *The surgeon, being convinced of the necessity of having recourse to operation, should proceed fully and unreservedly to lay before his patient the state of the case, and if necessary state the reasons that render an operation imperative, in order to obtain his consent, and that of his family. In the event of the patient refusing to submit, what course should the surgeon pursue? In this he must be guided partly by the nature of the proposed operation; and partly by the state of the patient, and his capability of forming a correct judgment of his case. If the operation be one of expediency, merely for the relief of an infirmity or the removal of an ailment, and does not directly jeopardize life, most certainly no surgeon would think of undertaking it without the full consent of his patient. If on the other hand it be an operation that is imperatively necessary for the preservation of life, in which the delay of a few minutes or hours may be fatal to the patient, as in the case of the proposed ligature of a wounded artery, or the relief of a strangulated hernia, and in which the patient not being aware of, or capable of being made to understand the necessity for immediate action, is unwilling to assent to the proposal, the surgeon truly will be placed in a dilemma of anxious responsibility; between allowing the patient to sacrifice to his ignorance or timidity, and attempting, perhaps unsuccessfully, to rescue him from inevitable death against his own consent. I believe the proper course for the surgeon to pursue under such circumstances, is to judge for the patient in a matter in which he is*

[18] American Medical Association, "Principles of Medical Ethics of the American Medical Association," (1903).

clearly unable to form an opinion, and to compel him, for far as practicable, to take the necessary for the preservation of his life. In the event of the patient being insensible, as after an injury of the head, the surgeon must necessarily take upon himself to act as the case requires. Children cannot be considered capable of giving an opinion as to the propriety of an operation; the consent of the parents is here necessary, and quite sufficient, and in their absence, the case being an urgent one, the surgeon must stand in loco parentis, and take all responsibility upon himself[19].

Therefore, as general recommendations before performing a surgical intervention, physicians had to inform their patients about the diagnosis (the state of the case), and the reasons for which the surgery was needed. If they refused the intervention, there were two main possibilities: (1) respect their wishes, if by that their life was not jeopardized; or (2) respect the duty to do good, if the surgical intervention was needed to save the life of the patient in the face of an imminent threat. The latter was justified by physicians not through a right to operate, as was often the case in Europe at the time (see the following chapters), but rather through the fact that most likely the patient was not able to make to right decision due to fear, ignorance, or timidity, and therefore their capacity to act voluntarily was diminished.

E.C. Franklin, in his work "The Science and Art of Surgery, Embracing Minor and Operative Surgery; Compiled from Standard Allopathic Authorities and Adapted to Homoeopathic Therapeutics…" (1867), devoted a specific chapter entitled "Consent of patient" to these questions:

A very important question, and one which admits of grave doubt, is as to how far a surgeon may be justified in assuming the responsibility of operating, when a patient is unwilling to give his assent. Of course, no one would think of performing any operation of complaisance without the full consent of the patient, but where an operation is immediately necessary to save life, as in a case of strangulated hernia or of injury requiring primary amputation, the surgeon's position is one of great perplexity. If the patient be a child, the consent of the parents is quite sufficient; if an adult, but unable from intoxication or other cause to judge for himself, the consent of a near relation or friend who is competent to decide the matter should be obtained; in the absence of the parents or other relatives, the surgeon must place himself as it were in loco parentis, and do fearlessly what he thinks

[19] John Erichsen, *The Science and Art of Surgery, being a Treatise on Surgical Injuries, Diseases and Operations*, ed. John Brinton (Philadelphia: Blanchard and Lea, 1854), 76-77.

best for his patient. If, however, an adult in full possession of his faculties refuse an operation, or if, in the case of a child, the parents refuse for him, I cannot think it the duty of the surgeon to persist in operating under such circumstance; he should remember that spontaneous recoveries do occasionally occur in the most promising cases, and that, on the other hand, that may very likely follow the most eligible best executed operation; and when the true state of the operation and the imperative necessity (humanly speaking) of the operation have been clearly and fully explained, I cannot think that the surgeon should be held responsible for the consequences of obstinate refusal on the part of the patient or his friends[20].

There is no specific mention made as to whether the relative able to give consent could have been a woman (such as a married woman for her husband, or a mother for their children). However, as Franklin used "parents" when discussing the consent needed to treat a child, it is possible to infer that the gender of the relatives was not highly relevant when seeking consent for a medical procedure. Most likely, this situation was determined by the fact that consent was seen as a formal procedure, not completely regulated.

In an article published in the Journal of the American Medical Association (JAMA) in 1890, entitled "Element of Consent in Surgical Operations*",* it was argued that, even if consent was an essential requirement before surgery to diminish malpractice claims, it was not enough in itself: "We incline to the view that the mere element of consent is not sufficient to absolve the medical man from responsibility, unless the operation is within the recognized limits of medical or surgical procedure. It will not protect the physician in performing bizarre operations, or in reckless experimentation"[21]. Therefore, to minimize the risk of malpractice suits, the surgeon had to (1) respect the consent of the patient (or his friends), and (2) perform a standardized medical intervention. Even if consent was primarily viewed as a protective measure for physicians from malpractice claims, some articles clearly linked it with the exercise of morality within medicine. For example, an article from 1867 entitled "Clitoridectomy and medical ethics" stated:

That the performance of clitoridectomy on a woman absolutely without her knowledge and consent, as detailed by Dr. West, is an ***offence against Medical ethics****, needs not be said. We suspect it is amendable to the*

[20] E. C. Franklin, *The Science and Art of Surgery* (St. Louis, Missouri: Democrat Book and Job Printing Establishment, 1867), 496-97.
[21] "Element of Consent in Surgical Operations," *Journal of the American Medical Association* XV, no. 11 (1890).

criminal law of the land. It is an offence against Medical ethics, also, to obtain the woman's consent, nominally, while she is left in ignorance of the real scope and nature of the mutilation, and of the moral imputations which it involves. Consent to a thing whose nature is not known, is like the consent of an infant or lunatic – null and void. Equally do we repudiate, as an offence against Medical ethics, the performance of such an operation, even with the consent, nominal or real, of the patient but without the full knowledge and consent of the persons on whom she is dependent, as wife or daughter.[22]

Therefore, obtaining a formal consent was not considered enough; it had to be, additionally, based on a proper understanding of the purpose and nature of the procedure, and its consequences, and had to be given by a person with decisional capacity. Therefore, by the 1860s, apparently, all the major elements of the modern theory of informed consent were present (information, understanding, voluntariness, and decisional capacity).

A generation later, Hornsby and Schmidt, in a work entitled "The Modern Hospital: Its Inspiration; Its Architecture; Its Equipment; Its Operation" (1914), made the procedural requirements governing consent much more specific. They recommended that no patient should be taken into the operating room before a series of conditions were met including:

Written consent for the operation, signed by the patient, if an adult, and in mental condition to give such consent, on the regular "permit for operation" form of the institution. If the patient is under legal age, eighteen years in females and twenty-one in males, or, if the patient is unconscious or delirious or in such mental condition as to be unable to realize the gravity of the operation, the permit must be signed by the responsible person nearest of kin available.; If there is no such person present or available, the facts must be stated to the superintendent of the hospital, who may use his discretion in issuing a special permit, on the face of which all the facts must be stated. This permit must be taken to the operating-room as a part of the regular record of the case. This permit must be had whether the anesthetic is to be general or local[23].

In obstetrics, an instrumental delivery of a baby could be performed only after the patient had given her competent consent in writing: "No instrumental delivery, or delivery by surgical interference, will be

[22] "Clitoridectomy and Medical Ethics," *Medical Times and Gazette*, (Saturday, April 13, 1867), 391-392.
[23] John Allan Hornsby and Richard Ernest Schmidt, *The Modern Hospital: Its Inspiration: Its Architecture: Its Equipment: Its Operation* (Philadelphia: WB Saunders, 1914), 339.

permitted under any circumstances without competent consent in writing of the patient; if the patient be incapable of giving intelligent written consent, same must be obtained from husband or other responsible relative, and, in the absence of any of these, the attending physician must avail himself of the counsel of the nearest available physician in active practice, both of whom shall sign a statement of the facts in the case"[24].

In the same book, the authors detailed struggles with implementing the procedure of written consent for any type of procedure, even minor, mainly due to strong resistance from physicians:

> *The Michael Reese Hospital has given much attention to this question, and has finally adopted a form of written consent to be signed by the patient, if an adult and in sound mind, and by the nearest responsible relative of the patient if the patient is a child or mentally incapacitated to decide whether or not an operation shall be performed. This permit form has been submitted to some of the best lawyers, and all of them agree that it has immense force as a moral deterrent, and some of the ablest men in the legal profession have pronounced it a legally binding instrument; at any rate, since it became the routine of the hospital to demand a written permit preceding every surgical procedure, there has not been an opportunity to test the validity of this permit form, because no case has ever gone into court against the hospital or its surgeons. When this permit was first proposed, there was objection to it on the part of some of the surgeons, who felt that it would frighten patients or their friends to the extent of making them refuse an operation. The results have not borne out this fear, and when it is explained to a patient or a relative that such a permit is demanded, even in the very simplest case, merely in order for the institution to be absolutely certain that no one is going to be operated upon without his or her consent, objections have fallen away, until now it is definitely understood by surgeons, physicians, patients, and the public that the hospital will not allow anyone to be operated upon without a written consent, not even if all the family, including the patient, express a willingness to have the operation done*[25].

Consent in Medical Research

Medical experimentation on human beings has a long history, with the first recorded example claimed to have occurred almost 3000 years ago[26]. However, to our knowledge, the first document to detail procedural

[24] Ibid., 343.
[25] Ibid., 464.
[26] Christopher J. Bulpitt, *Randomised Controlled Clinical Trials* (Boston: Springer, 2012), 5.

matters regarding human experimentation was written less than 1000 years ago, in Avicenna's "The Canon of Medicine" (1025). At the beginning of the second volume, Avicenna detailed a series of general conditions that the testing of new medicines should fulfill, presented in a chapter entitled "On knowledge of the potency of drugs through experimentation"[27]. These guidelines, although based on an entirely different approach to medicine and to the knowledge of the human body in general, contained some elements that still form part of today's methodology of medical research, including the need for at least two study groups to assess the usefulness of a drug, the need for reproducibility, and the need for human experimentation to test the efficacy of certain drugs[28]. The fundamental ethical principle underlying medical experimentation was beneficence, as in the Hippocratic tradition; however, whereas in the Hippocratic tradition the physician was viewed as the ultimate resource for knowledge, in The Canon, knowledge had to come from experiments, as the subjective opinion of a physician could be erroneous[29]. A systematic use of clinical trials to obtain generalizable data can be identified from the 18th century[30], and soon afterwards concepts such as the placebo, randomization, and informed consent became fundamental concepts in medical research. As these ideas emerged, various physicians and researchers tried to develop a structured framework for human experimentation, some of which involved detailing ethical concepts. Gregory set out, in "Observations on the Duties and Offices of a Physician and on the Method of Prosecuting Enquiries in Philosophy" (1770), a series of general guidelines, including that (1) animal studies (with an emphasis on pharmacology and toxicology) were needed when similar experiments could not be conducted on humans; (2) medical data should be based on objective information, obtained from experimental data or previous clinical cases; (3) using analogies could be beneficial, but they should only be employed to develop a hypothesis; (4) medical research should be collaborative, including teams consisting of researchers with different sets of skills; and (5) risks were inherent components of medical experimentation[31]. Percival, in his "Medical Ethics", suggested the following as the primary justifications for

[27] Sorin Hostiuc et al., "Avicena's Canon of Medicine. Research Methodology and Ethics," *Studia Universitatis Babes-Bolyai-Bioethica* 60, no. 2 (2015).
[28] Ibid.
[29] Ibid.
[30] Bulpitt, 50-8.
[31] John Gregory, "Observations on the duties and offices of a physician and on the method of prosecuting enquiries in philosophy," in *John Gregory's Writings on Medical Ethics and Philosophy of Medicine*, ed. John Gregory (Springer, 1998).