Introduction

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Informed consent is a gold standard in Western medicine. There are nuances to its application under diverse contexts, be they in public health, clinical research or the bedside. Since the 1960s, the backbone of informed consent in research has been firmly enshrined. Its formulation and justification have evolved since the Nuremberg code and the Universal Declaration of Human Rights. In medical research, we can find guidelines on informed consent in numerous international documents including, for instance, the Belmont Report (1978), Council of Europe's Oviedo Convention (1997), The Universal Declaration on the Human Genome and Human Rights (1997) and constant updates from Council for International Organizations of Medical Sciences (CIOMS), the World Medical Association's Declaration of Helsinki and the UNESCO Declaration on Bioethics and Human Rights (2006).

Despite the general acceptance and practice of informed consent in medical intervention and research ethics, there are still challenges to overcome and concerns that need further evaluation. For instance, informed consent needs to be tailored to the individual and is a process rather than a formality. The ways to communicate, present information will, therefore, depend on the literacy and cultural context of the subjects and patients. A genuinely informed decision needs to be free and enlightened, and a simple signature is not enough. There must be a trusting relationship between the patient and the physician–researcher who, at the same time, must consider the vulnerability of being someone who is ill and in need. We must address the false hopes and desires of participating in trials that may or may not be curative. There is a greater awareness of the exercise of autonomy in vulnerable groups of subjects such as volunteers, children, migrants and ethnic minorities. We need to consider the communitarian nature of decision-making in many cultures.

As a Research and Innovation program (2014–2020) of the European Union, Horizon 2020 funded the i-CONSENT consortium to improve the information that patients receive from clinical research by creating

personalized and innovative informed consent.¹ Being a partner in this venture, the UNESCO Chair in Bioethics and Human Rights investigated “the ethical gaps, barriers and challenges currently present in obtaining informed consent in biomedical research, prior to the administration of vaccines, and during translational/clinical vaccine research involving human participants.”² Within this project, the UNESCO Chair has a particular focus on the multicultural and interdisciplinary dimension of informed consent. This volume, therefore, collects the papers generated from i-Consent as well as other related articles.

Together with some of the i-Consent partners, the UNESCO Chair held its 6th International Bioethics, Multiculturalism and Religion Workshop on the topic of Informed Consent on 21–23 February 2018. Bioethical and religious scholars from Buddhism, Confucianism, Hinduism, Christianity, Judaism and Islam came to Rome to discuss the key challenges and the requirements of informed consent in clinical research. They identified some of the challenges present in obtaining informed consent from patients/subjects in different, challenging cultural contexts representing minority groups and vulnerable populations.

Multiculturalism and relational autonomy

The first section of this book collects four articles on the topic of informed consent in cross-cultural contexts. In these essays and reports, there is an unease with the overtly individualistic conception of autonomy that undergirds the process of informed consent championed in Western medicine. The process of obtaining consent in different cultures, minors, family dynamics and community settings may require more than a straightforward signature of the patients or their proxies. These different situations mean that an over-emphasis on individual rights and autonomy might be detrimental to truly informed consent. The articles evince the need to consider autonomy as relational—where family members, community and other stakeholders can play an essential part in the consent process.

Already in the report generated for the Horizon 2020, i-Consent project has a section that focuses on how multicultural background can influence informed consent. The challenges regard the prospective patients’ ability to fully understand the disclosed information as well as the procedural barriers that prevent them from giving genuinely informed consent. It discovers that there is a need to examine cultural and social variables when assessing the ethical validity of this consent process because a monolithic, individual-centred version of autonomy in the Western contexts may not be congenial to vulnerable migrants or cultural groups. The report recommends a new look at “communal” and “relational” autonomy where deliberation and

legitimacy of a decision not only belong to a single person but involves the community—such as the family—to which the subject belongs.³

The first chapter from Garcia and Garasic looks at informed consent from the angle of human rights and mental privacy. Advances in biotechnology and neuroscience propitiate the need to consider additional rights that protect cognitive liberty, mental privacy, mental integrity and psychological continuity. These new requirements will have implications for informed consent in the context of religious diversity.

Garasic and Macioce's chapter on "Informed Consent and Minors in a Multicultural Society" looks at the unique needs of minors who cannot give full, independent and competent consent as they are not yet grown-ups. In cross-cultural and multi-religious settings, this legal age distinction can create additional problems of interpreting individual autonomy. The case of the underaged minors calls for an adaptation of the notion of self-determination to include relational autonomy.

Daverio's chapter on "Community engagement in the informed consent process in global clinical research: international recommendations and guidelines" delineates how informed consent in global clinical research will require engagement with the community. This involvement in collaborative research will need further analysis and formulation of ethical goals and guidelines towards meaningful participatory processes. The author discusses the main strategies for community involvement in research settings internationally and the steps to work towards a more relational view of the self.

Finally, Tham and Letendre confront the cultural shift of individual to relational self in the West and the implications of decision-making and informed consent in healthcare. The article traces the history of Western medicine from "paternalism" to autonomy in the physician–patient relationship as a result of rapid advances in medicine. Due to different historical and legal demands, patients became gradually more involved in the decision-making process. Nevertheless, it soon became apparent that informed consent may turn out to be a procedural or legal requirement that does not holistically embrace all the patient's situation. To correct this imbalance, they observe in the literature a more nuanced shift from the individual to the relational self where a richer conception of moral agency is emerging.

Religious traditions on informed consent

In the second section of the book are the papers submitted to the workshop in Rome by the six major world religions and their cultural ambits.

According to Zhang, Buddhism does not have any canonical norms on most bioethical topics, which are Western constructs. Buddhism would allow for the rights language of informed consent to protect the individual agency, truth disclosure and self-determination in healthcare decisions. However, the Buddhist tradition is wary of any individualist notion of a substantial self as someone who can make real free choices. Since ontological selfhood is elusive, any exaltation of autonomy would be problematic. The Buddhist vision of interdependence sees absolute self-determination as untenable since we cannot fully define the self except in relation to others. Buddhists consider that we are predetermined and conditioned socially, and karmic causality is at work without our knowledge. As Zhang says:

In the case of informed consent, it is very often difficult for physicians (as well as for patients) to determine if a patient's deferral of decision-making is his/her own choice or the result of formative influences of the family. It follows that the patient's capacity for intentional action is also questionable. Voluntariness involves the idea of "free will," which would be problematic for Buddhists, and medical decision-making based entirely on patient-centered orientation would be problematic for Buddhists as well.

According to Ruiping Fan, Confucian ethics is based on virtues rather than on rights, liberty and equality so prominent in Western ethical systems. However, Confucianism will accept legitimate human rights that protect individual interests to enhance virtuous living. Fan thinks that neo-Confucianism can accept minimalist rights developed along the lines of Rawls that would include the right to life, security, liberty, conscience and equality before the law. However, these are not to be conflated with full-fledged individual rights understood in the West. Confucian China considers medicine as the art of *ren* or benevolence. In this understanding, the training of the physician is meritocratic and virtue-based. Patients implicitly trust the benevolence of their doctors, and informed consent is, therefore, absent in this relationship. Fan claims,

Chinese physicians must have gained consent, either explicitly or implicitly, from patients and their families in order to conduct medical treatment, but it is also clear that obtaining such consent before treatment has never been formally and clearly required in the tradition.

Besides, Confucianism emphasizes shared family decision-making in healthcare, which can come into conflict with the liberal understanding of autonomy. At the same time, the patients prefer to involve family members in making

healthcare decisions, which does not necessarily mean medical paternalism. Instead, it implies that Confucian patients can autonomously accept familism as the best choice to make these decisions. Autonomy and self-determination are not part of the Confucian virtue-based ethical system.

Lunstroth looks at the classical texts of “Hinduism” for the grounding of consent in research. India is a secular state that accepts biomedical ethics, despite being Western constructs, as a political structure to protect the vulnerable. Since Hindu ethics is only relevant to the householder stage of life, which is of the political order guided by *dharma* as order, law or duties, only the *Arthashastra* of *Kautilya* contains a systematic theory of political/legal order. This text can offer insight into the *dharma* of the scientific enterprise and the role of informed consent. As such, Hinduism evaluates research ethics through the ethos of sacrifice.

Lunstroth is highly critical of the current arrangement, where a subject often becomes a data point for the sake of scientific advances. There is a commodification of human bodies as tools to be exploited. Benefits for the future generations are also not evident, as the results of the research are often oriented to commercial benefits or privatized as intellectual property. The research subjects are sacrificed and do not receive the benefits for themselves or for their community, and they cannot readily negotiate or sue the researchers. As Lunstroth comments,

The emphasis of the rule on the sacrifice being completed suggests the state is interested in maintaining the integrity of the sacrificial transaction . . . the drug company sacrifices the individuals who “consent” to participate. The company strips value from them, aggregates and then monetizes it for itself. The god is the neoliberal economic system that awards greed, and the sacrifice usually works.

Hence, in the context of the *Arthashastra*, informed consent in research is an impure sacrifice since the research subject is often ignorant, the researchers and industry are somewhat corrupt and the political order is too compromised to protect its citizens.

We now turn to the monotheistic religions. The Jewish discussion of informed consent relied on rabbinical sources, according to David Heyd. The underlying question deals with the question of whether one can sacrifice physically to help or save someone else. This tradition seeks a balance between self-preservation and self-care, and the supererogatory social commitment to promote the public good. Contemporary rabbinic opinion on informed consent holds that doctors need to consult patients or family before they enter experimental trials. There is also a presumptive force for the doctor to safeguard the patient’s life. While Judaism accepts the practice

of informed consent, it rejects its theoretical basis of autonomy since God alone is sovereign over our lives or our bodily parts. Heyd explains,

The requirement of consent in medical treatment is based on the potential suffering and harm to the body and on the duty of self-care rather than on the idea of the absolute control of human beings over their lives. Thus, informed consent is not a major principle in the doctor-patient relationship, since there is a duty of the doctor to heal and a parallel duty of the patient to be healed. Being cured is not a matter of choice or of personal autonomy.

Akin to Muslim practices, Judaism allows for “different amounts of information to different subjects based on their individual degree of anxiety.” Finally, informed consent depends more on legitimacy—mediated through the rabbis—than on individual autonomy.

Laura Palazzani recognizes that informed consent in research, as practised in the West, is compatible with the Christian worldview. The values of human rights, dignity, respect for privacy, freedom to decide, justice, risk and benefits, beneficence and non-maleficence found in the secular framework resonates with the Christian ethical framework. However, Palazzani notes that Christianity derives these bioethical principles from the concepts of God’s creation, human finitude, *imago Dei*, our ability to know the truth and act according to it and the infinite value of human life and its eternal destiny. The dignity of human life also implies the possible choice to sacrifice oneself in research out of charity and solidarity. It is a laudable act for the benefit of the common good. Hence, Palazzani believes that informed consent is:

inspired by Jesus, who cured the sick *with compassion, generosity, and understanding*. Christians believe that disease and suffering are trials from God to bring them closer to salvation through death and into His grace. Scientific research should be done for the purpose of serving those who are ill, not solely or primarily for the benefit of the researchers.

Nevertheless, there are also aspects of informed consent that might diverge from the secular approach. The protection of vulnerable groups due to the severity of the illness, age, gender, socio-cultural conditions must also extend to the most fragile member of the human family—the human embryo and foetus. Hence, research done on them is highly contentious. The Christian and mainly Catholic understanding of human sexuality precludes involvement with specific techniques of contraception or assisted

reproductive technologies, especially if they could harm the embryos. On certain occasions, the physicians and researchers should have recourse to conscientious objection to abstain from participating in some acts which, as stated before, are essential values for Christian living where objective truth and salvation are at stake.

Padela shows in his chapter that Islamic moral theology will support aspects of informed consent although it would not ground this ethically from the principle of respect for autonomy. Instead, something equivalent to the basis of informed consent will come from Islamic theology of moral liability in front of God. Moral liability (*taklīf*) means standing before God in judgement and being morally responsible for one's actions. For Islamic bioethics, every action has moral significance, and patients need to properly consider both the mundane and afterlife ramifications of participating in medical research. Hence, informed consent processes can aid Islamic individuals to live morally.

Islamic theology aside, Muslim states and culture are also varied, according to Padela. Many of them have pronounced communitarian ethos, with responsibilities of medical decision-making residing in the broader community. Padela writes,

In many Muslim societies the patient-doctor dyad is often not the only locus of decision-making. . . . People trust their relatives and community members and value interdependence, therefore limiting decision-making within person-centric rights can deny the value attached to such relationships.

Muslim patients do not expect or desire a great deal of explicit information. Paradoxically, too much information can leave them to feel uninformed and can even generate distrust. Moreover, Muslim societies need to ground ethics regulations within Islamic law. For instance, Saudi laws make repeated references to the *Sharia* as a source of guidance on research ethics.

The inadequacy of the autonomous self

These chapters have shown that many religious traditions challenge the Western idealization of the autonomous self. They prefer a more relational or communitarian understanding of doctor–patient or researcher–subject relationship. Western medicine and its current gold standard of informed consent may not adequately address the theoretical scepticism by different religions and cultures towards its underlying grounding of autonomy.

As these chapters have shown, Eastern religions are more sceptical of the bioethical discourse based on human rights while the monotheistic religions

are more compatible with the informed consent discourse.⁴ Despite external similarities and acceptance of informed consent at a practical level, there are deep theoretical and foundational problems. The concept of the self in different religions can explain how these difficulties arise.⁵ In Eastern cultures, selfhood is illusory or derives meaning through interdependence with nature, family or community. This understanding can pose a challenge to the atomic self from which informed consent is derived. Western monotheistic religions define self-identity with a transcendent God. They tend to be more legalistic in their approach and derive legitimacy from the scriptures or religious authority. In all the religions, the language of sacrifice is prominent in the framework of research ethics, where the patients act virtuously in solidarity for the greater good of fellow humans. Informed consent points not only to earthly existence but also to the less tangible questions of life, be they in the imperceivably small embryos or that of the mysterious afterlife.

From a practical point of view, these differences in the foundational values are becoming more pronounced with migration and increased affirmations of cultural groups when they participate in clinical research. A swift from individual to relational autonomy may be more consonant with the greater research populace who tend to frame healthcare decisions and understanding of illness and well-being in religious terms. Embracing these ideas can offer a more nuanced improvement of the readability, design and obtaining process of consent. As different chapters in this book show, this shift will better align the conscious and unconscious cultural biases of the investigators with the multicultural and religious variables of the subjects. This shift can proffer a cross-cultural vision of vulnerability that can enhance knowledge, communication and empathy in consent to research. Consequently, more individualized approaches will help frame multi-layered informed consent which includes these global perspectives.

Notes

- 1 This book has been elaborated under the EU project i-CONSENT (<https://i-consentproject.eu>) that has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No. 741856.
- 2 The full report can be accessed here: <https://i-consentproject.eu/wp-content/uploads/2019/01/D1.4-Ethical-issues-concerning-informed-consent-in-translational-clinical-research-and-vaccination.pdf>.
- 3 *Ibid.*
- 4 See J. Tham, K.M. Kwan, and A. García (eds.), *Religious Perspectives on Human Rights and Bioethics* (Dordrecht, Netherlands: Springer, 2017).
- 5 See J. Tham, C. Durante, and A. García Gómez (eds.), *Mind, Genes and Self: Religious Reflections on the Impact of Emerging Technologies on Human Identity* (Abingdon, UK: Routledge, 2018).