

Article 6 of the UNESCO Universal Declaration of Bioethics and Human Rights: A moral force in South Africa

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The United Nations Educational, Scientific and Cultural Organization (UNESCO)'s Universal Declaration on Bioethics and Human Rights (UDBHR) was accepted unanimously in 2005 by the world community, consisting of 191 member nations. This means that the declaration is currently the first and only bioethical text to which the entire world, including South Africa (SA), has committed itself. Despite this, little or no attention is paid to this declaration in SA. According to UNESCO, the declaration should be brought to the attention of the community because knowledge will promote more effective application of its principles. In an attempt to answer the call of UNESCO, article 6 of the declaration is discussed briefly in this article. It is clear that the principle outlined in article 6, as a human right, comprises two important components, namely giving information and giving consent. These two ethical values must always be applied during medical intervention and research. Where these principles are applied, human autonomy is confirmed and human dignity is expressed. Although the UDBHR is not judicially enforceable in SA, its universal nature offers a clear moral force in the bioethical debate in SA.

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Existing research aims to investigate and give an outline of article 6 of the Universal Declaration on Bioethics and Human Rights (UDBHR),^[1] as drawn up by the United Nations Educational, Scientific and Cultural Organization (UNESCO). In article 6, the UDBHR explicates informed consent as a universal ethical principle as well as a fundamental human right.^[2,3,10] The problem statement of this investigation is as follows. Firstly, the UDBHR was accepted unanimously in 2005 by the world community, consisting of 191 member nations, which means that the declaration is currently the first and only bioethical text to which the entire world, including South Africa (SA), has committed itself.^[2,4,5,10] Stanton-Jean *et al.*^[6] emphasise the fact that the world community views upholding the dogma of informed consent, in solidarity with each other, as the duty of all communities. The principle of informed consent occupies an essential position in the following international codes: Nuremberg Code (1947) and Declaration of Helsinki (1964).^[3]

The added value of the UDBHR could be demonstrated in the words of Veatch^[14] when he says: 'the International Bioethics Committee (IBC) heard from representatives from religious/spiritual perspectives including Confucianism, Judaism, Hinduism, Islam, Buddhism, and Catholicism. The result is the first truly international, representative codification of norms for bioethics that the world has ever seen. Rather than reflecting the norms of the professional groups or national, religious, or ideological bodies, the universal declaration can legitimately claim to speak for virtually all citizens of the world (at least through the representatives working on their behalf)'. Ethicist and human rights expert J M Vorster's^[7] statement concerning the universal declaration also holds true for the UDBHR, as he postulates that: '[i]t can be said that without doubt this Declaration has become an important document in ... history'. Despite this, little or no attention is paid to this declaration in SA. Recently, a very important book was

published by two prominent SA academics, titled *Bioethics, Human Rights and Health* without paying any attention to the declaration.^[8] Secondly, a recent study by the American Institute on medicine as a profession indicated that gross human rights offences took place quite recently in the American army, where medical personnel infringed on the right to autonomy and informed consent by force-feeding military prisoners.^[9] The International Bioethics Committee of UNESCO (IBC) made the following statement: 'Medical education in general and bioethics education in particular should pay particular attention to the principle of consent and to its applications ... all persons should know that this principle is to be respected. Individuals, groups, communities, institutions and corporations, public and private, should therefore be made aware of the importance and relevance of this principle for research and healthcare ... Moreover, since experience in many domains has shown that laws or regulations are only effectively enforced if they are backed by action in education, training and information ...'^[2,10]

The purpose of this research is to join in UNESCO's mission and to form part of the social responsibility initiative of teaching this universal right and the ethical principle so as to promote the way this basic right and the ethical principle is applied in SA.^[2,6,10] To do so, this article focuses on the concept of informed consent as it is explicated by UNESCO, and attention is therefore given mostly to official UNESCO literature. In this study, attention is paid to the basis of informed consent as well as the notions of information and permission.

The foundation

Kollek,^[3] one of the authors and official UNESCO declarer of the UDBHR, emphasises the fact that the principle of consent has an anthropological foundation within the UDBHR, and explains it as follows: 'Therefore, article 6 on informed consent is directly related to article 3 (Human

dignity and Human rights) and article 5 (Autonomy and Individual responsibility) of the Declaration. None of these articles stand alone, they need to be seen in conjunction with one another, expressing different dimensions and aspects of central normative demands.'

One of the official syllabi used by UNESCO in teaching the UDBHR worldwide (Bioethics Core Curriculum, section 1) confirms the statement above.^[10] From this, it is clear that the right and principle of individual consent arises from the right and ethical value of autonomy (freedom), while giving information and consent expresses human dignity.^[2] UNESCO's *Casebook on Bioethics and the Holocaust* confirms this truth.^[11] This point of departure by UNESCO is strongly supported by the SA Constitution, as well as the *SA Patients' Rights Charter*, which emphasise dignity and freedom from which informed consent ensues.^[8,15,16]

Attention is subsequently paid to the meaning of informed consent according to the UDBHR.

The meaning

According to Kollek,^[3] in the UDBHR, informed consent is viewed as a complex communication process that comprises information and consent respectively.^[2,6,10] The order is as follows: firstly information, secondly consent and then intervention or research ('prior to' according to article 6.1,2).^[1] Information is a definite prerequisite for consent.^[2]

What is understood by information, according to the UDBHR?

Article 6 of the UDBHR declares that informed consent comprises adequate information ('adequate information', according to article 6.1,2).^[1] Adequate information is important because thorough information maximises good decision-making and minimises the possibility of harm.^[1-3,10] What is adequate information according to the UDBHR? Here, only the core elements are highlighted and a distinction is drawn between the subject of information and the object of information.

Firstly, the focus is on the subject of information (doctor and researcher). It is the duty of the person responsible for the medical intervention or the research to initiate the process and provide information. Providing information is compulsory, and the doctor must therefore make a comprehensive attempt to inform the patient.^[2] Therapeutic privilege does not enjoy the same support as it did previously in the global bioethical context, owing to its misuse in the past and the fact that it stands in contrast to the autonomy of the individual. It is therefore only allowed in exceptional instances.^[2,11] UNESCO is of the opinion that the doctor should also consider his or her professional experience and abilities as important information. This information could contribute to a relationship of shared trust and respect for confidentiality.^[2,10]

Secondly, the object of information (patient, research subject) is explored. To give valid permission or consent, the person must have the rational capacity to comprehend the information (as opposed to 'persons without the capacity').^[1-3,10] UNESCO points out that it is difficult to determine with certainty whether the person understands all the information.^[3] Stanton-Jean *et al.*^[6] make the following very important statement: 'The level of difficulty in which the informed consent is situated posits that it is difficult, if not impossible, for large proportions of the world population to understand what they are agreeing to by giving their 'informed

consent'. Beauchamp and Childress,^[12] however, state the following in this regard: 'From the fact that actions are never fully informed, voluntary, or autonomous, it does not follow that they are never adequately informed, voluntary, or autonomous! Stanton-Jean *et al.*^[6] support this in principle and suggest (which is important in the SA context) that the comprehension of information can be promoted by in-depth conversations as well as by making use of aids such as graphs, sketches, cartoons, pictographs and/or videos. It may happen that a patient or a participant in research may doubt whether he or she completely understands the information (possible goals, risks, advantages, expected results, or even their own rights). In such a case, a mediator can be used to analyse the information, and in doing so support the patient or participant in his or her decision.^[2]

The UDBHR distinguishes between medical intervention and scientific (medical) research in article 6.^[1,2,10] With regard to the content of information, a patient in the face of a possible medical intervention should be given information on the following matters: diagnosis and prognosis, qualities and process of intervention, expected advantages of intervention (prevention, cure, palliative), possible unwanted side-effects of the intervention, possible advantages and risks of alternative interventions, or no intervention.^[2,11] Persons who donate their bodies or organs after their death also need to receive as much information as possible on all the relevant aspects.^[2] Living donors of organs must receive comprehensive information about the possible short- and long-term consequences of such a donation.^[2]

Before medical scientific research can take place, the following information requires attention: the goal of the research, the methodology of the research, the duration of the research, the expected benefits of the research for the participant (if any), the expected benefits of the research for others, the potential risks related to the research, and possible discomfort or inconvenience. Furthermore, information related to potential risks must receive special attention.^[2,10,12]

- It is advisable to determine participants' opinions on whether they would want to receive the incidental discovery of negative information before the research commences.^[6]
- Before an individual makes any tissue (blood, urine, saliva, etc.) or data (written, electronic questionnaires, interviews, genetics) available for research, the person must receive comprehensive information on the usage of the tissue and/or data. This includes the goal for which it will be used, when and where it will be used, whether it will be coded (made anonymous) and whether he or she has the right to withdraw tissue/data at any time.^[2]
- When previously collected tissue or data is to be used at a later stage in another study, information on the new situation must be provided. If this is not possible, an ethical committee must determine whether it is justified to do away with the right.^[2,6]

Some patients choose not to exercise their right and they do not receive information prior to intervention or research; therefore, they entrust themselves to the doctor or researcher entirely.^[2] Stanton-Jean *et al.*^[6] point out that using one's right to ask not to receive information has become part of the global bioethical discourse and is justified on the grounds of the individual's autonomy. It is desirable that official ethical bodies help to decide whether not exercising the right to information is advisable in a specific case.^[1]

Information must have the qualities indicated below: it needs to be qualitatively sound. In other words, it needs to be as clear and as complete as possible ('provided in a comprehensible form', UDBHR, article 6.2).^[1,2,10] Too much complex information (e.g. complex terms) must be avoided on the one hand, and too little and oversimplified information on the other.^[2,3,6] It is strongly advised, especially in places such as SA, that the information be conveyed in the national or local language and structured as logically as possible.^[2] Information must be individual and sensitive when directed at the audience. Hence, the information needs to be adjusted according to the circumstances and the condition of the patient; when a serious diagnosis is conveyed, tact and choice of words are exceptionally important.^[2] The time and place when conveying information is equally important.^[3]

UNESCO asserts that the person must be informed that he or she has the right to withdraw permission or consent at any time during the process of intervention or research without having to provide reasons for doing so ('be withdrawn ... at any time and for any reason', UNESCO, 2006, article 6.1, 6.2).^[1,2,10]

What is understood by permission and consent according to the UDBHR?

It is the duty of the person who will perform the medical intervention or do the research to obtain the necessary consent,^[2,10] which comprises several components.

UNESCO emphasises the principle that the person who gives consent (before giving said consent) may not be under any form of external pressure ('free' according to UDBHR, article 6.1,2).^[1,2,10] The person must give consent freely either to be treated or to participate in research, and he or she must also be able to refuse freely.^[2,3] It must be ensured, as far as possible, that no person is coerced into participation in research.^[2,10] UNESCO lists various inadmissible forms of coercion, namely:

- Social status or asymmetrical relations can result in situations where some people do not have the frankness to ask questions or the freedom to refuse treatment or participation in research, or the freedom to express their uncertainty.^[2,6,10] The same holds true for people who are incarcerated. Concerning medical research, the IBC has a general rule that persons in compulsory confinement may not be involved in research.^[2]
- Impoverished people may consider participating in medical research in order to receive medication or financial support. In this regard, the IBC points out that (healthy) participants from various countries come to Europe to participate in research. For this reason, numerous countries have registers in place to monitor people's frequency of participation in medical research, and in this way these people are protected against possible side-effects and non-voluntary participation in medical research.^[2] According to UNESCO, extraordinary rewards should not be offered.^[2]
- The IBC points out that in poor economic circumstances where there are bad medical services (shortage of doctors, lack of infrastructure, insufficient medication, and poor training), the right to informed consent might not always be implemented (according to the *Mail & Guardian*, only one of 394 hospitals audited between May 2011 and May 2012 in South Africa met all the acceptable standards, while under a third of staff were deemed to treat patients reasonably, with a quarter described as being caring).^[13]

For this reason, many people have no choice. The IBC highlights the fact that this may not serve as an argument for neglecting the right and the ethical principle – ways of implementing the principle need to be devised.^[2]

- UNESCO warns against the possibility that the social expectations of a family or a community could pressure a person into making a decision they deem acceptable or good according to others. Under these circumstances, a family in distress can emotionally pressure a person into donating an important organ or into refusing a life-saving blood transfusion.^[2,10]
- Tension reigns within global bioethics between individualism and community values. In some communities, the leaders of the communities make the (coerced at times) decisions on behalf of the individual and these decisions are not questioned due to respect for their leaders' age and wisdom, and the belief that the leaders want the best for the community.^[2] Kollek^[3] points out that: 'different cultural understandings of informed consent have been appreciated by the Declaration'. The point of departure is stated in article 6.3 of the UDBHR: 'In no case should a collective community ... substitute for an individual's informed consent'. In other words, although social or collective community decision-making is a right, it may never replace the right of an individual to make a decision. The IBC and Kollek^[3] summarise it as follows: 'the order of precedence must be clear: the interests of medicine and society must never prevail over the interests of the patient ... it should always remain possible for individuals to refuse to collaborate and any exertion of pressure should be avoided if they refuse to join such a programme or wish to withdraw from it.'^[2,3,10] This is in line with article 12 of the UDBHR, which states that cultural diversity and pluralism may not be used to infringe on the fundamental rights and freedom of the individual.^[1]

According to UNESCO, freedom and voluntariness can be promoted through in-depth discussions between the healthcare worker and the patient. Probing dialogue brings about clarity and improves the relationship between the parties involved.^[2,6] The IBC^[2] of UNESCO points out that considering a decision (or consent) and requesting and obtaining permission is not a 'one-time affair'. With regard to invasive medical interventions, the IBC^[2] comments as follows: 'It is advisable in such cases to give the patient time to think the question over.'^[2,10]

The abovementioned process (providing information, comprehension and coercion) first needs to be completed before a formal decision can be made. When an individual decides to proceed, consent must precede any medical intervention or research according to article 6 of the UDBHR.^[1] It is of great importance that permission be granted, since it confirms the autonomy and the definitive will of the person involved.^[2,3,10] It is necessary, however, to note here that the UDBHR declares in article 6 that consent is only required in relevant circumstances during a medical intervention ('where appropriate', UDBHR article 6.1), while definite consent is always required before medical research ('express ... consent', UDBHR article 6.2).^[1,2] Hence, one can distinguish between implicit and explicit consent.^[2]

- Implicit consent, 'where appropriate', has two possible explanations:
- In the first place, with various routine, simple non-invasive medical interventions in the doctor's consulting room, information and the patient's consent can be considered to be self-explanatory, for example when taking the patient's blood pressure.^[2,10] The

International Bioethics Committee of UNESCO points out that the more invasive the medical intervention and the greater the physical, mental and socioeconomic consequences, the more definite and formalised the consent needs to be.^[2]

- In the second place, the reality that obtaining consent (as discussed above) in a crisis situation is not always a possibility is acknowledged. A patient may be confused or unconscious. In these circumstances, consent for medical treatment is considered less critical or problematic as any reasonable person would give consent.^[2]

Explicit consent during research may be either written or oral consent.^[2,3,10] It can be in the form of a consent form or an oral agreement in the presence of witnesses.^[3] In some cases or cultures, only a gesture is sufficient.^[2] Before human tissue or personal data are collected, definite consent must be obtained. Tissue and data for which consent has already been obtained and which needs to be used in later, dissimilar research, requires consent once again.^[6] According to UNESCO, something like 'overall prior consent', where the future use of tissue and data is left to the discretion of the researcher, does not exist.^[6] It is advised that, where applicable, information and consent be managed by an ethics committee.^[2,3,10]

Consent may be withdrawn at any time without having to provide reasons for doing so ('may be withdrawn ... at any time and for any reason', UNESCO, 2006, article 6.1,2).^[2,3] After having withdrawn consent, the person may not, by any means, be done an injustice or be treated with bias ('without disadvantage or prejudice', article 6.1,2).^[2]

In various countries, it happens that individuals give consent in advance (advanced directives) with regard to specific medical interventions or no intervention in the future. This is done in case such an individual is no longer capable of making decisions, is very weak or can no longer function in any way.^[2] According to UNESCO, this expresses the individual's autonomy and forms part of the principle of informed consent.^[6] Persons who wish to donate their bodies or organs after their death must give the necessary consent prior to their death.^[2,10]

An important theme that surfaces in the application of article 6 of the UDBHR is the temporary suspension of an individual's autonomy and self-determination. UNESCO notes that this derogation of rights does not happen frequently and needs to be applied very strictly according to the guidelines in article 27 of the UDBHR ('Exceptions to and provisions set out in this declaration, in particular in article 27', UDBHR article 2;27).^[1,2] In this regard, UNESCO posits the example of individuals who need to be put in quarantine by the government due to the possible spread of an epidemic.^[2]

Conclusion

The UDBHR confirms the fact that the principle of informed consent is a universal human right and not simply the opinion of the medical profession (e.g. World Medical Association) or a certain continent (e.g. the European Convention on Human rights and Biomedicine). Although the UDBHR is not judicially enforceable in SA, its universal nature offers a clear moral force in the bioethical debate in SA.

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