The fallacy of “universal” standards of care within a model of anthropological medicine

[La falacia de estándares de cuidado “universales” en el marco de un modelo de medicina antropológica]

por Delia Outomuro (*), Eduardo Rodríguez (**) y Fernando Lolas Stepke (***)

(*) Academic Unit of Bioethics. Faculty of Medicine. University of Buenos Aires
(**) (***) Interdisciplinary Center for Bioethics, University of Chile

Resumen
El cuidado los sujetos de investigación es un tema crucial en bioética. Se afirma que quienes investigan en países en vías de desarrollo deben garantizar los mismos cuidados que en el país patrocinador de la investigación; de otra manera la investigación constituiría una forma de explotación. Sin embargo, las normas universales no reconocen diferencias culturales en la salud.

Sostenemos que el positivismo es la base filosófica de las normas universales y que éste subvierte uno de los más importantes principios de la medicina: que no hay enfermedades sino enfermos. Por lo tanto, un modelo antropológico de medicina y una filosofía que incluyen el Lebenswelt (mundo de vida) ofrecerían un marco teórico más adecuado que el positivismo para la discusión sobre las normas de cuidado en investigación.

Aunque ciertas guías ética internacionales confirman la obligación del uso de normas universales, se advierte cierta vaguedad en sus reglas. Sería recomendable que las guías éticas dejasen una brecha para excepciones en relación con los valores y pautas culturales de cada país. Estas excepciones deberían estar sólidamente justificadas y los comités de ética deberían jugar un papel crucial en decidir sobre ellas, así como en posibilitar el diálogo entre los investigadores y las autoridades sanitarias del país con el fin de establecer las orientaciones de diagnóstico y tratamiento según las prioridades y preferencias locales.

Palabras clave
Estándares de cuidado – ética – investigación – países en desarrollo – medicina antropológica

Abstract
Standards of care for research subjects are a crucial topic in bioethics. Some researchers argue that research subjects in developing countries should have the same standards of care as those in the country sponsoring the research; otherwise it would constitute a form of exploitation. Nevertheless, universal standards do not recognize cultural differences in health.

We argue that Positivism, the philosophical basis of universal standards, turns upside down one of the main mottos of medicine, which is that “there are patients and not illnesses”. Hence, an anthropological model of medicine and a philosophy that includes the Lebenswelt (world-of-life) would offer a framework more suitable than positivism for the discussion about standards of care.

Though some ethical international guidelines confirm the obligation to use universal standards, there is some vagueness in their rules. It would be recommended that ethics guidelines leave a gap for exceptions in relation with the use of universal standards. These exceptions must be strongly justified and ethical committees must play a crucial role in deciding about them as well as in making possible the dialogue between researchers and public health authorities in order to establish diagnostic and treatment guidelines according to local necessities and preferences.

Key words
Standards of care – ethics – research - developing countries – anthropological medicine
Standards of care for research subjects are a crucial topic in bioethics. Some researchers argue that research subjects in developing countries should have the same standards of care as those in the country sponsoring the research; otherwise it would constitute a form of exploitation. Others say it may be not only impossible (even technically) to offer the same standards of care, but also inconvenient. Research efforts should not be considered less ethical if they offer solutions appropriate for developing countries. The universal standards of care may have ethical strong arguments but, because of economic inequities, offering such a standard may act as a form of coercion or manipulation interfering with voluntariness in informed consent. They do not recognize cultural differences in health either.

We will examine these statements and their philosophical basis. Also, we will try to identify some problems in relation with the requirement of using universal standards of care with the intention to show the necessity for a new theory as framework in bioethics. Many ethic discussions have recently focussed on standards of care and although some ethical international guidelines confirm the obligation to use universal standards, there is some vagueness in their rules. This is an important subject because these guidelines are used by ethical committees to evaluate research proposals.

What are we talking about: Care or treatment?

International guidelines sometimes refer to care [1] [2], but others refer to treatment [3] when they deal with standards. Care and treatment are not synonymous. Care is a wider concept that involves treatment but also implies other things such as nursing, nutrition, social assistance, environment comfort, etc. It is interesting to underline that the Declaration of Helsinki 2000 (paragraph 29) alludes to “the best current prophylactic, diagnostic and therapeutic methods” and not to care. Any discussion should therefore specify if reference is made to care, to treatment or to prophylactic, diagnostic or therapeutic methods.
Shapiro and Benatar analyzed five international research ethics documents (National Bioethics Advisory, CIOMS, Declaration of Helsinki, UNAIDS: Ethical Considerations in HIV prevention vaccine research, Nuffield Council on Bioethics) and demonstrated that “the phrase ‘standard of care’ is often addressed obliquely and remains poorly defined. These international guidance documents thus do not sufficiently address the broader concept of SOC [standards of care]” that these authors defend [4].

**Standards of care: One for central countries and another for peripheral countries?**

It is said that there are different standards of care (or treatment). At least two can be discerned: the one that is available in the country sponsoring the research, which is usually estimated as the universal standard, and the one accessible in developing countries. As for the latter, in some cases treatment may be nothing. Also, it is said that “research cannot be considered in a vacuum, and that the role of the research in developing countries differs from that role in resource-rich countries where research participants generally have access to adequate health care” [4].

This dichotomy is a fallacy since differences between the rich and the poor exists not only between countries, but also within any country. We find people with high levels of income in Bolivia, and poor people in London. Consequently, the distinction must be made between rich and poor people independently of the place where they live. Rich people have access to the same treatments in every country and the lack of assistance is a common denominator for the poor.

**The placebo puzzle**

Another topic to analyze is the use of placebo mainly because this is the usual treatment in developing societies. It is said that “placebo-controlled trials was the fastest and most
efficient way to obtain information of relevance to the areas where the research was being conducted” [5]. This is not completely true. If we review the bases for methodology of research we can see that the only advantage of using placebo is that we will need a lower number of subjects than using a controlled group with some treatment. In same cases it will be the fastest way but not always. In relation to efficiency the question is darker; it is possible to obtain reliable information even with a treatment controlled group. The debate remains open, and this is a good example of how technical and methodological questions overlap with ethical ones in research.

The best standard of care: Is there any?

The next question we need to elucidate is the meaning of “the best standard of care”. As we have already mentioned, standards of care in developed countries are usually judged as the best ones.

This premise underlies Shapiro and Benatar proposal. They say: “the definition of SOC in research that we propose ties somewhere between the highest standard achievable with unlimited resources and the miserably low (sometimes non-exist) standards characteristic of very poor countries” [4] and further on “that the ideal of first world health care cannot be achieved immediately in developing countries should not be a deterrent to efforts to raise existing levels of care. By setting high ideals and working towards them, the standard of care could be progressively ratcheted upwards” [4]. Then, they describe seven steps to guide improvements: to involve the community, to determinate the elements of SOC, to form partnerships, to provide proved prevention and care, antiretroviral therapy (we have to remember that they are talking about HIV-AIDS), to ensure benefits to both participants and community and, eventually, to link research to enhancing justice and to increase funding. At the end, they recommended “to achieve ethical standards that are high as scientific standards” and “as it is unlikely that an overall universal SOC can be rapidly achieved in research projects in developing countries, the goal should be to implement
reasonable standards that are significantly higher than available in the host country, and
close to standards in the sponsoring country” [4].

As the same authors recognized, involving the community means to have discussions with
community members in order to find their health priorities and their care preferences (that
is well pointed out in the second step they mention). The first and the second steps are
decisive and if they are not only a declaration of principles and are actually respected, it
could be possible that the idea of the best care or treatment fade away.

The point of view that care and/or treatment available in the first world are the best is
sustainable only within a positivistic framework, a paradigm in which there are no
differences among patients. If they have the same illness, then they need the same
treatment. The simple-minded positivism turns upside down one of the main mottos of
medicine, which is that “there are patients and not illnesses”. The greatest expression of this
kind of thought is evidence-based medicine.

An alternative view is a philosophy that includes what Heidegger calls Lebenswelt (world-
of-life), i.e. an anthropological model of medicine [6]. This paradigm proclaims that each
patient is unique because a patient is a person, and a person is more than a body; a person
has a biography and is irreplaceable. The best treatment for Mary may not be the best for
Susan because Mary and Susan have different life histories, and their cultural values and
customs may vary.

This point is important and should be considered. Ethical reasoning must differentiate
between medical best proven intervention based on evidences for a particular disease and
patient choices. The principle of non-maleficence involves respecting both. Some medical
treatment can be suitable, but the patient may not be able to choose it and his/her wishes
should be respected. An illustrative example: the treatment for larynx cancer may be
surgery or radiotherapy. The surgical treatment provides more probabilities of survival but
leaves the patient without voice. A manual worker may perhaps choose this alternative, but
it is possible that a public person leans for radiotherapy because, in his/her future project, this option implies a better quality of life, even if he/she has to sacrifice quantity of life.

Another example is the case of treatment for percreta placenta. As it is known, according to evidences the best treatment is to remove the uterus. But it is possible to use cytostatics in order to destroy the new tissues and, if this treatment fails, to use surgery. Some women may prefer to have this chance and refuse the treatment regarded as the best one. On the other hand, a woman who has offspring and is in the pre menopause may prefer surgery.

The conjoint consideration of treatment options and patient wishes is as problematic today as in former times, where therapy was more limited. What it is said about patient's preferences is appropriate to cultural groups. Differences among them must be recognized and respected. Otherwise, thinking that there is a treatment considered as the best might be understood as a way to impose a “technological or scientific imperative”.

**Standards of care: a kink of naturalistic fallacy?**

Naturalistic fallacy is a well know critic made to utilitarianism. Moore criticizes Mill saying that his utilitarianism theory equates good with some other sensitive property and thus considers ethics like a natural science. The fallacy is the failure to distinguish clearly between two planes: one descriptive and other prescriptive. Goodness belongs to the last one and is not reducible to non-ethical entities. Known as "the naturalistic fallacy", this proposition states basically "ought cannot be derived from is". The "ought cannot be derived from is" proposition is based on the idea that good, (the premise of ought), is not a natural property, i.e. it is unobservable in nature, and thus it is an indefinable concept and unexplainable in terms of natural science.

In the same way, it is possible to consider that the prescription of universal SOC is also a naturalistic fallacy. Hyder and Dawson pint out that:
“Standard of care is a concept borrowed from the medical-legal context that denotes the level of conduct against which a physician’s or health provider’s treatment of a patient will be judge in determining whether certain conduct constitutes negligence. It generally means ‘what a reasonably prudent physician (or specialist) would do in the same or similar circumstances’. Defined in this way, it can meaningfully describe the types or level of treatments provided to patients in the clinical setting but it might not serve as a justification for what should be provided to participants in research” [7].

These authors affirm it is necessary to distinguish between the use of a descriptive concept and the use of a normative concept of SOC. They also say that, in a legal context, the concept is used in both ways: the usual medical practice and the legal obligation to provide care at that level, i.e. at the customary level in that specific context of medical practice. We agree and add that there is a substantial difference between research and assistance contexts. In the first one we “you generate yourself” to phenomenon, we produce an intervention and so we are responsible for it. We have more responsibility in the development of what we decided to create (the research context) than in a medical practice context.

It is very interesting the distinction made by Alex London, and quote by Hyder and Dawson, between: local de facto standard, local de jure standard, global de facto standard and, finally, global de jure standard. The local de facto standard for a community has to be set by the current medical practices of that community. The local de jure standard for the same community has to be determined by medical experts in the host community as to which interventions have been proven most effective. But this standard should take into account both biological and non-biological factors that may influence the effectiveness of an intervention previously tested outside the host country. In contrast, global standards (de facto and de jure) would be determined by medical experts in a larger medical community.

It could be said that global standards belong to the positivism framework while local standards rescue cultural values and work within the anthropological medical model that was presented before.
Axes of health system in a developing country can be deconstructed in two aspects: the *structure* of the health system (basics or preventive level and higher or curative level) and the *efficiency* of each specific level. Problems in anyone of these two parameters may affect the health care that is available:

“Two problems may arise in such scenario: the scope of services available and the efficiency of the health system […] An inspection of a specific area in a developing country may reveal what is the current care available in the area; but that may not be the ‘standard’ either because a different type of service is not planned for that level of health system, or because it is a result of existing inefficiencies and unfortunate circumstances” [7].

The authors propose that the minimum level of care that should be provided to a control group is the national standard of care defined as “the level of care that ought to be delivered under conditions of appropriate and efficient referral in a national system” [7]. If there is no national guideline for the disease involved in the research, it should be discussed between researches and local authorities before research is undertaken.

Towards the same basal conditions in different countries: is it possible? Who is it useful for?

According to Shapiro and Benatar “if trial communities rank clean water, food supplements, and housing above medical interventions, sponsors and other partners might contribute to these background improvements in addition to more medicalised interventions. *Ensuring baseline standard of living and health care across study sites will also contribute to more generalisable study results*” [4].

Research methodology distinguishes three types of variable: dependent, independent and intervener. Independent variables are those that seek to explain changes observed in dependent variables. Intervener variables are those that might play a role in the phenomenon to be explained but they are put under control in the research. These variables are identified according to our cultural values and scientific knowledge. Then, it is possible
not to recognize some features as relevant factors because they are outside our framework of analysis. For example, the effectiveness of a vaccine in the prevention of an infection disease may be only apparent and the real cause of this effect may be due to some variable which make the difference between cultural groups (clean water, food rich in proteins, etc.). Therefore, to provide what is in relation with such variable to the community would be more important than the vaccine.

Evidently, the principal health problems of developing countries are different from those affecting developed nations. Nevertheless, drugs that will be used in developed countries are constantly proved in the third world. The reason is pointed out by Ángeles-Lleneras et al:

“A lo anterior [la diferencia en los problemas de salud], se suma una mayor cantidad de sujetos ‘disponibles’ para participar en cualquier investigación respecto de una menor población en países industrializados dispuestos a participar. Es por ello que para la industria farmacéutica, estos países representan un terreno fértil para ‘proponer’ sus proyectos de investigación, lo que les ofrece una mayor cantidad y menor tiempo en la obtención de resultados, sean estos positivos o no” [8].

“To the above-mentioned [the difference in health problems of], sink a bigger quantity of subject ‘to be available’ to participate in any investigation in comparison with a smaller population in industrialized countries willing to participate. This is why, for the pharmaceutical industry, these countries represent a fertile land for ‘proposing’ their research projects, they offer them a bigger quantity and smaller time in obtaining results, either positive or negatives.

[The quote translation is our]
means to achieve an end. A person can never be treated as a thing, i.e. as a means even when the purpose might be good. For instance, research may search a medicine against cancer and because of methodological features the control-group might receive a placebo even when there is some kind of treatment for that pathology. Of course, obtaining knowledge is a good purpose, but if we use placebo we are considering people as a means. It is forbidden by the categorical imperative. This is the reason why placebo-controlled trials that were conducted to test an intervention to reduce mother-to-child transmission of HIV were judged as unethical [4].

In contrast, some researchers argue that if trials like the one conducted to test interventions to reduce mother-to-child transmission of HIV had not been conducted, none of the women would have received an effective treatment. In other words, they say that giving some people the treatment under study is better than doing nothing because, at least, someone receives treatment and benefits.

In the same way, it is argued that if new therapeutic (or diagnostic or prophylactic) methods are not tested in people even under conditions which are not the best, then this will limit scientific knowledge and the world will lose a chance to fight illness.

These arguments reflect on a utilitarian point of view. For this philosophy the principle is “the major happiness for the major number of persons”. Therefore, sacrificing someone in order to save more people is correct, it is fair. Utilitarianism is common in medical practice. Medical decisions in emergency (e.g. triage) or in the unit of intensive care, when there is place for only one patient, and we have two or three who need the same resource are cases in point.

Within the framework of utilitarianism someone could do an attempt to rescue some features of Kantianism in order to conciliate both theories. Dignity is what makes the difference between persons and merchandises. Persons have dignity while things have price. Persons have dignity because they are the unique beings which have autonomy, i.e. their dignity lies on their autonomy. Then, if we want to respect persons’ dignity we must
respect their autonomy. As inform consent is a rule that derivates from the principle of autonomy, its respect implies the respect for dignity. Following this reasoning, it would be enough for avoiding ethical conflicts. If persons agree in running risks during a trial, even the risk of receiving nothing as treatment, there would be no unfairness.

Nonetheless, this reasoning is incorrect. Kant would say that a person who accepts such a thing has no autonomy; he/she is an incompetent and must be protected. Nobody with real autonomy could do something like considering him/herself as a means, as a thing. According to Kant, a person is autonomous when he/she respects the categorical imperative. In this context, the categorical imperative may be enunciated in the following terms: *Act so as to use humanity, whether in your own person or in others, always as an end, and never merely as a means* [11].

It is necessary to remember that meaning of autonomy from liberalism (and utilitarianism is a liberal philosophy) is completely different from Kant’s point of view. From this ideology autonomy means liberty. Autonomy and liberty are synonymous and each person may do whatever he/she wants with the only limit of not harming another person. For liberals, running irrational risks, harming oneself or committing suicide is not forbidden.

Any attempt to conciliate utilitarianism and Kantianism is probably an unsuccessful task. This is a reason why, perhaps, we should try to find another framework for bioethical reasoning, a framework beyond principialism and its roots (Kantianism and utilitarianism). As we have pointed out, a philosophy less universalistic that consider mainly the context and an anthropological medicine could be more helpful in dealing with the bioethical dilemmas. This task exceeds the purpose of this paper but it is a challenge that deserves being faced up to.
Principle of Justice: is it actually respected?

Other problem to address is equity in the selection of subjects for research. Principle of justice orders that risks and benefits must be shared equitatively among the whole population; otherwise the rich are benefited and the poor carry all risks. It means that selection of patients should be done in developing as well as in developed countries. It also means that patients of all social classes should be selected. It is well know that patients from poor social classes have been always used in research and medical teaching and this practice violates justice:

“La desigualdad social emerge en la práctica médica desde el primer momento del aprendizaje profesional...Los sujetos que reiteradamente son usados en la investigación son obtenidos en asilos, orfelinatos, cárceles, hospitales públicos para indigentes, cuarteles, etcétera. Al plantear estos casos no lo hago desde una consideración ética, no porque no pudiera hacerse, sino porque lo que me interesa es ponderar la red de relaciones sociales e ideológicas que la práctica médica genera y que no destaca objetivamente como tal, pues tiende a pensar su práctica en términos casi exclusivamente técnicos” [12].

“Social inequality emerges in medical practice from the first moment of professional learning ...Subjects habitually used in investigation are obtained in asylums, orphanages, jails, public hospitals for indigent, barracks, etc.. When outlining these cases I don't make it from an ethical consideration, not because it could not be made, but because what interests me is to ponder the net of social and ideological relationships that medical practice generates and that doesn't highlight objectively as such, because it spreads to think its practice of almost exclusively technical terms.” [The quote translation is our]

Notice that the proposal of using a national *de jure* standard is also useful to avoid exploitation of poor communities within a developed country:

“In developed countries such as the US, there are numerous examples of local deficiencies in medical care, particularly for groups that are poor, lack health insurance, or are members of ethnic minority groups. The implications of the national standard of care concept in a country like the US is that researchers working in poor communities may not substitute the concept of 'locally available care' for the national standard in medical care that is recommended for a given health condition” [7].
There are also other points linked with justice. When the research takes place in a developing country, interests for the country must be considered, also if the product of research will be available for the population when the research is finished. Nevertheless, the requirement of CIOMS 2002 that new drugs prove effective by research must be made “reasonably available” to the population where the research took place is very difficult to fulfill in practice, especially in a world in which there are enormous differences in socio economical status. One way to approach this goal is that health authorities must make agreements with pharmaceutical companies and make dispositions to diminish costs in order to make new drugs available.

According to Ruth Macklin [13], in order to protect vulnerable populations from the danger of exploitation we must recur to the concepts of “distributive justice” and “justice as reciprocity” The concept of “distributive justice requires that risks and benefits of research must be distributed with equity (give to each one what he/she needs) among all persons and groups in society. The concept of “justice as reciprocity” requires that subjects of research receive benefits because of participating. It would not be justified that a patient who has received placebo during the study, at the end of the study would not received the drug which research has proved being effective. There is exploitation when rich companies take advantage of the vulnerable, using them for their own purposes without adequate benefits to compensate them.

**Why universal standards of care might not work under the current circumstances?**

Three reasons are at least argued to support the statement that universal standards of care should not be applied: technical features, risks of inequities and the possibility of promoting undue inducement.

A universal standard of care is possible only from a positivist framework. But even within this model, it may be impossible to use the best treatment. For example, the gold standard
(the best one) for the diagnosis of lung thromboembolism is arteriography but it is less used than gammagraphy, which involves fewer complications.

On the other hand, offering such standards could promote greater inequities:

“Where services are improved in the research context, a dual SOC results within a community. Research participants may have easy access to free health care for problems unrelated to the research, in contrast with long waits and lack of essential supplies in the public system” [4].

However, it is interesting to distinguish between “research context” and “assistance context”. In same cases, when there is already a proved treatment, it would be right to provide “apparent” dual standards, for example, in testing a new antihypertensive drug. In these cases we ought to provide special assistance to the research group because we are not sure about the effectiveness or the harmlessness of the new drug. Persons who are running the risk of testing the drug must be looked after with special care. This point leads us to the next topic: the undue inducement.

Many ethical guidelines for research revolve around the dignity of the person. For instance, Declaration of Helsinki 2000 states that “life, health, privacy and person’s dignity” should be the main principle of every medical research (article nº 10) and that “in medical research involving human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society” (article nº 5) [14].

The same stance takes the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine; its article nº 2 says that “the interests and welfare of the human being shall prevail over the sole interest of society or science”, which means a primacy of the human being [15].

All these guidelines are based on a Kantian philosophy according to which a person must never be a means. However, it may be difficult to protect human dignity under the current
circumstances of inequity in developing societies (either developed or developing countries). As it is known, poor people practically have no access to health care services or if they do, the care they receive is not the same as the one received by patients who can pay for it. If we offer them the kind of care available for rich people because it seems to be the best one according to “universal standards”, this offer could act as coercion: “higher SOC than otherwise available may be seen as an undue inducement to participate in a trial” [4]. In other words, researchers could manipulate patients by offering them care (nurses, comfort, food, medicines, etc.) that they would not have if they do not accept entering the research. This is common among HIV-AIDS patients in Latin America. Also, this is why oncology and AIDS patients claim to be included in a research; sometimes, it is the only way to obtain treatment. Informed consent is not really free under these conditions. Therefore, we have to be careful when offering the best care with the purpose of protecting persons because, perhaps, we are not protecting but manipulating them.

It is interesting to point out that Declaration of Helsinki is mute all this topic while other guidelines recognize this possibility. Guideline 7 of CIOMS says: “…The payments should not be so large, however, or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgment (‘undue inducement’)” [3]. Paragraph 44 of the Nuffield Council on Bioethics affirms that the division line between inducement and benefit is very fine [2].

Conclusions

The discussion around standards of care provided for participants in research is not closed. It is a crucial topic in bioethics and surely there are other aspects to consider beyond those we have explained. Some preliminary conclusions can be advanced:
1) Care and treatment are not synonymous. Care is a wider concept that involves treatment but also implies other things such as nursing, nutrition, social assistance, environment, comfort, etc.

2) The Declaration of Helsinki 2000 (paragraph 29) alludes to “the best current prophylactic, diagnostic and therapeutic methods” and not to care.

3) Within the concept of treatment we have to include therapeutic, prophylactic and diagnostic methods are included.

4) The dichotomy between two standards of care, one for the country sponsoring the research (which is usually estimated as the universal standard and as the best one) and another for developing countries is a fallacy since the differences between rich and poor exists not only between countries, but also inside any country.

5) In fact, there is not one best standard of care because we deal with patients and not with illnesses. Patients are persons and they are unique because of their biographies and different cultural values and customs.

6) Positivism turns upside down one of the main mottos of medicine, which is that “there are patients and not illnesses”.

7) An anthropological model of medicine and a philosophy that includes the Lebenswelt (world-of-life) offer a framework more suitable than positivism and principalism for the discussion about standards of care. This seems to be the spirit of the Nuffield Council on Bioethics when its report recommends that the context in which research is conducted be carefully evaluated when setting the standard of care for the control group in a research project [2].

8) Also, an anthropological model of medicine allows community participation which is strongly recommended by many ethic guidelines (although Declaration of Helsinki and the Nuffield Council on Bioethics are silent at this point):

   "Researchers/sponsors should involve community through trial design and implementation” (National Bioethics Advisory Commission, recommendation 2.3)

   “Important to involve community members in decisions around benefit/risk, informed consent, responsiveness to health needs (CIOMS, guidance 1, 10)."
9) The proposal of the national standard of care - defined as “the level of care that ought to be delivered under conditions of appropriate and efficient referral in a national system”- as the minimum level of care that should be provided to a control group is a very good attempt to solve the bioethical problem of double standards.

10) It is necessary to differentiate between medical best proven interventions based on evidences and patient choices.

11) Kant’s philosophy underlies the position of those who defend the Declaration of Helsinki. The basic idea is that a person is never a means to an end.

12) Those who say that if you do not test new therapeutic (or diagnostic or prophylactic) methods in people even under conditions which are not the best then you will set limits on the scientific knowledge and the whole world will lose the chance to fight illness, are thinking from an utilitarian positivism.

13) Placebo-controlled trials are not necessarily the best ones. It is possible to obtain reliable information even with a treatment controlled group.

14) Principle of justice is not respected when research subjects are only selected from poor people.

15) Using universal standards of care(considered the best ones) does not work for these reasons:
   a) Even from a positivist model it is very difficult to determine which the best one is.
   b) Patients would prefer a treatment that is not considered the best one according to evidence and we must respect their decisions. Patient choices and cultural differences have priority from an anthropological medical model.
   c) Even agreeing with Kantian philosophy, it is possible to fail in our attempt to protect human dignity under the current circumstances of inequity in developing societies. Researchers could manipulate patients offering them care (nurses, comfort, food, medicines, etc.) that they would not have if they do not accept to take part in the research.

16) Therefore, the last and main conclusion is that, perhaps, it would be recommended that ethics guidelines leave a gap for exceptions in relation with the use of universal
standards. Of course, these exceptions must be strongly justified and ethical committees play a crucial role in deciding about them. Ethical committees also develop a decisive task in making possible the dialogue between researchers and public health authorities in order to establish *de jure* diagnostic and treatment guidelines according to local necessities and preferences.
Bibliografía


