Updating articles

Bioethics of biomedical risks

Miguel Kottow

Abstract - Informed consent (IC) for medical procedures and research protocols bases on a benefit/risk evaluation. Sophisticated therapeutic procedures and advanced biomedical investigations may entail considerable risks, even if benefits for participants are marginal or non-existent, especially in non-therapeutic studies. To facilitate participants' recruitment, it has been proposed to stress non-specific medical benefits or vaguely appealing to common good that, thus, would foster what stimulates false therapeutic expectations. Information on risks is incomplete, mitigating the magnitude or possibility of negative effects, and by resorting to minimal riskcs doctrine to recruit both autonomous people and those with impaired mental competence. Cultural and socioeconomic barriers between researchers and the population from poor nations, which host the studies, have promoted the idea of *vulnerable ones*, defined as the incapacity to look after their own interests that unduly establishes paternalistic relationships, approaching to colonialism. Ethics committees should be stringent in their evaluations to protect those who are incorporated into procedures of uncertain benefits and unknow risks or higher than informed

Key words: Free and informed consent. Clinic trials as topic. Ethics. Biomedical research. Risk.

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Preliminary sociological considerations

The systemic sociologist, N. Luhman, stresses the difference between danger – possible damage due to external or environmental cause – and risk, which is the perception of a threat caused by a decision. Risk has human origin and, therefore, identifiable, danger comes from the surroundings and it may not be known. A decision is risky when eventual damage affects who makes the decision, but when the damage affects others, these face danger, as they do not control the determining circumstances of the threat[1]. Human interference may convert natural dangers into risks with attribution of responsibilities (assismic constructions), as well as human origin risks may turn out uncontrolled and take the features of danger (global warming).

Whoever takes a risky decision does it to get a benefit for oneself or, if altruist, to benefit others, while it is not

rational to take risks if it is not with a benefical goal, which explains why rational evaluation of a decision that might have negative effects is based in pondering the benefit/risk ratio. The counterpart of risk is not safety, since the safest way to prevent risk of a posible damage is not to take a risky decisión, but this means to asume the risk for not getting desired benefits. If an individual prefers not incurring in the risk of taking a plane, he/she assumes the risk of not getting the advantages that flight speed would have meant.

Prevalence of risky endeavours in complex societies led to shift them into *risk societies*[2], where the responsibility of the State weakens to protect citizens and to cover or to compensate those harmed. Remembering that the counterpart of risk is not safety but danger, it should be spoken on contemporary societies shaped into communities in danger as citizen faces political, technical, strategic decisions where he does not have a saying, and whose negative effects he cannot precaution himself by resorting to protective social structures.

Citizen insecurity comes, in large measure, from the loss of institutional protection, becoming an issue of individual autonomy both in taking risks and in assuming the burden to finance protection against them. All ecological misery of the current world comes from pragmatic decisions that are risky (the investment or programa may fail), but that turn out into dangers (threatening situations or straight forward harmful) to citizenship. The benefits remain in hands of those who have the power and the means of accessing it, while all share negative effects – pollution, resources exploitation. The weakening and the insolvence of the contemporary State reduce its protecting roles in such way that citizen lives in uncertainty, insecurity and unprotected[3].

In clinical medicine and in clinic studies the noncompliance with the ethical features of the risk sociology is observed often. People are committed in taking risks even if they do not mean any benefit to them. Therapeutic or scientific activities are decided by others than those affected, in such way that they are submitted more to dangers than to risks of the procedures that they had accepted, without any control to avoid or reduce these dangers. Finally, patients and research subjects do not count on enough protection against possible complication that may occurr during or after completion of procedure to which they have consented.

Biomedical risks: general features

The biomedical risks analysis carried out here concentrates in the clinical and scientific concept referred to the probability of undesirable effects for patients who accept a treatment or for subjects who consent in taking part in a biomedical study.

In this context, risks are important to identify and to take precaution, being preferable at times to avoid procedures where benefits are more uncertain and reduced than possible complications. It is from current work that epidemiological concept of risk motivated major polemics between positivist epidemiology, linking risk probabilities for subjects susceptible to external factors, and critic epidemiology developed in Latin America by Arouca, Almeida, Ayres, Breilh, Castiel and others. It sees risk as a synergic threat by environmental determinants that shift toward unprotected individuals and absence of preventive mechanisms[4]. It is worth mentioning that there is also in the epidemiology deep discrepancies between positivist concept of risk, preferred among English speakers, and the more ecological view of risks deriving from enviornmental factors particularly weakened in countries laggin behind in development.

The reflection on biomedical risks precedes and dulls patients' voluntarity to accept therapeutic procedures issue, and recruitment for clinical trials with potential negative effects on studied subjects. Both, Reichsordnung standards (1933)[5] and the Nuremberg Code (1947), emphasize voluntary consent as the core condition to intervene in the human body with therapeutic and scientific goals. This view has been ellaborated in biomedicine under the doctrine of informed consent (IC), which undergoes a major distortion when it signals that

if gotten in good form (the IC) transfers the responsibility of negative hazardous event from medical doctor to patient[6]. Emphasis is place not as much in the posible damages as it is in the voluntary acceptance of suffering them if they occur.

The concepts of patient's informed decision in face of several medical alternatives and on informed consent in taking part as research subject bases in the pondering of benefits versus unwanted effects risks. It is still valid that

[The] *risks-benefits pondering is a crucial component in planning and control of medical research and public health*[7], but these elements have been submitted to distortions and rethoric manipulations that need to be analysed in order to protect patients, research subjects and communities[8].

Both in biomedical practice and research, emphasis on informed consent is moving away from benefits, acknowledged as uncertain, and quite often only marginal or clearly nonexistent, to the exclusive presentation and biased evaluation of risks. Much of this change in emphasis is due to the institutionalization of medical accountability, to the proliferation of ill practice judgment and to legal suits regarding large pharmaceutical firm. The fear of the consequences of placing patients and research subjects to risk has led to a remarkable concern over the issue both in the academic

world and among practicians and researchers. It is often noticed that proposals and practices targeted to caution primarily researcher in how to manipulate, hide or minimize risks in order to get patients and research subjects' consent and participation. Equally worrisome is the use of arguments that seek the weakening of the individual and social perception of risk in order to foment and to justify clinical trials that serve less to medical knowledge than to corporate and academic interests. In the other hand, in face of certain practices such as artificially assisted reproduction, for instance, there is doctrinary positioning that exacerbates maternal and infant risks as to dissuade the use of this technique. It is not an exageration to highlight that real or perceived risk manipulation became a powerful tool, which serves more pragmatic interests than common good[9]. The issue of biomedical risks takes a new dimensión, forcing bioethics to step in a dull area and full of uncertainties, to which this current reflection refers.

Deterioration of ethical standards in research

The IC, which was the core concern in Nuremberg and of the first *Helsinki Declaration* in safekeeping patients and research subjects, is turning out into defensive tool for the agent as means to reduce and avoid accountability for possible damages that may be produced. By presenting to patients and research subjects the decision to accept eventual damages under circumstance of uncertain or absent benefits. Thus, involved risks get a higher weight, mostly by delivering these decisions to dependent individuals – the so-called captive population – who see or fear their autonomy to be cut by the clinical status in which they are, the voluntary consent been dulled by *pressures* felt by the patient scared by his dependence and suffering[10]. Under these conditions, it becomes irreal the benefits/risks pondering, been necessary to carry out a more criterious evaluation of posible negative effects that may harm the affected and the way to inform them.

The ethical standard of research with humans began in 1933, having as historical benchmark the Nuremberg Code prepared at the end of WW II, and the first *Declaration of Helsinki* (1964). After 5 reviews, the Declaration presents its most recent version (Seoul, 2008), which has been negatively evaluated by Latin American authors for tolerating the growing unprotection in clinical studies of participants [11,12].

The *Common Rule*, based on the Belmont Report, is, in the USA, the only biding standard in research ethics, to the point that the *Food and Drug Administration* (FDA) gave up in attaining itself to the *Declaration of Helsinki* or to any other existing document[13]. Even though the *Common Rule* requires a balance between individual benefits and risks for research subjects, it

admits that these benefits can be replaced by important scientific benefits that, by been so vaguely defined, are postulated in unsounded way, destabilizing research subjects protection. In pre-clinical researches (or Clinical Stage I) with healthy subjects who will not have medical benefits, risks to undergo may be justified with presumed social benefits, but in clinical studies with patients where the doctrine of *Duty of Personal Care* governs that places beforehand professional care of patient's medical needs in face of a research protocol requirements.

The development of bioethics standard in research with humans is not altogether a happy one, since it tends to favor researchers' and patrons' interests instead of protecting subjects and communities into whom research is carried out. It is symptomatic the trend to tolerate research in medicine and anciliary disciplines (biomedicine), which increases, often stealthily, potentical unwanted complications to the point where research with humans is characterized ever more as a risk science. This evolution is detectable in three vectors: a) research programs increase potential negative effects, both for studied subject and for their social repercussions; b) semantic and cultural efforts are intensified to reformulate and to mitigate risk elements of studies, both clinical and epidemiological; c) incidence of new lines of research with possible severe complications increases. Pharmaco-genetics, neuroscience and nanotechnology are outstanding among the latter.

Risks in biomedical research

Medical researches, above all pharmacological, tend to comply with the severity of medicine based in evidence, incorporating to clinical medicine knowledge only what has been researched through randomized control trials (RCT), including the much debated recommendation of using placebo as comparator[14]. The English expression *randomization*, used in Spanish as *"randomización"*, translated into Spanish texts as "aleatorización". The risk increase for research subjects, who are, by definition in clinical studies, ill people who require treatment, relies in leaving in the control group and, therefore, in *therapeutic orphanage*. If they keep any therapy, this therapeutic orphanage could still be considered, as relative, but it would be absolute if they only get inactive substances, if they are targeted to surgical simulations or fulfill an initial period of pharmacological bleaching. The resource to objectivity, to statistical analysis and massive data collectioin means increase in number of people submitted to uncertainties and possible undesirable effects of research. The strategy of multicentric studies is an additional factor to increment the number of people exposed to inherent risks to genuine research whose exploitation is marked by the unknown.

Biomedical research has undergone changes and migrations that involve greater risks among growing difficulties to detect and to prevent them. Research, leaving universities and scientific centers, is carried out by commercial agencies that are guided more by profit than by ethical requirements[15]. At same time, scientific activity moves to countries with precarious development where research ethics is less institutionalized, communities and individuals live impinged by preexisting inequalities, malnutrition, insufficient medical coverage, lack of legal protection, factors that make them more susceptible to risks and unwanted consequences[16,17].

The growing interest for front line studies and critical topics, such as instrumental control of reproduction, the neuroscience, the use of virus in genes transfer, the introduction of artificial or animal origin organs, are not only risky technically for individuals, as well as they have social repercussions and, consequently, transmit the threats of unwanted effects from individuals toward the community. Neuroscience, for example, is set to investigate the control of reactions and behavior in soldiers[18], inevitably entails social consequences – programming of torturers, soldiers insensible to the action of killing – as biogerontology of longevity will also have, and eventually transhuman cloning or the possible transmission of animal diseases to the human being through xenotransplants.

The ethics sheltering of epidemiological research is newly coined. Anecdotal but illustrating is that the *Council for International Organizations of Medical Sciences* (Cioms) presented a regulatory document of animal research in 1984, inasmuch as its *International Guide for Epidemiological Studies Ethical Review* it is only published in 1991. Reflections and codes on ethics in public health and in regards to epidemiological research and community risks that may be presented, are shown very late in ethical deliberation[19].

Epidemiology attempts to participate in the scientific method in medical research, by joining the laboratory - molecular epidemiology – to adopt random control trial method, or to give in to the rigor of internal validation, which is the application of knowledge within populational scope. The community studies have their own risks, such as disclosure of scientific data that may destabilize local cultural beliefs, to interfere with social peace, to unleash negative discrimination process and the mercantilization of information gotten in supposedly scientific studies.

Even when ethical presumptions of epidemiological research differ from those of clinical studies, the closeness between both scientific branches implies that they must abide similar ethics requirements and

risks analysis. The risky feature of every research with human beings, as well as the conditions that exacerbate these risks, increase its incidence in more complex researches, and charged with uncertainties, debilitated population, have had the paradoxical effect to mitigate the concerns with those risks and to reduce the protection of the threatened.

Risks evaluation

Risk criteria most used in clinic and in research with human beings have been two. Generally, there is pondering between benefits/risks ratio, accepting higher risks when benefits are more substantial, but respecting a second criterion that set limits to the magnitude or probability of acceptable negative effects, above all when benefits are marginal or uncertain. With the advent of highly sophisticated medical treatment, and researches that replace observation for invasive intervention in human body, it became more complex and unpredictable to evaluate the relation between possible benefits – therapeutics or cognitive – and the collateral damages that may occur.

The deterioration of benefits

Leaving aside what refers to compensations and incentives to participate in researches, it is worth remembering that the firts *Declaration of Helsinki* (1964) explicitly distinguished between clinical *therapeutic* studies – carried out for the medical benefit of involved patients – and the non-therapeutic ones that recruit patients for researches that have nothing to do with their clinical status. The importance of this distinction was confirmed by requirement of thinkers such as H. Jonas, stating that *the experiment in patient could eventually* only *take place if it relates* with his illness (originally in italics) [20].

This quite reasonable prescription of not submitting ill people to additional risk of a clinical study, except if in direct medical benefit or for a better knowledge of illness, has been diluted by the statement that every treatment has research elements as well as the later always includes therapeutical features, which is an inaccurate opinion that protection to patients remains. The merely rethoric feature of such observation becomes patent when these very same researchers insist to separate clinical ethics from research ethics, moving the patient from the shelter of medical treatment to misfortune of research [21].

When research subjects are those who seem to get mixed up with the cognitive purposes of research with those of a better quality medical care, they are accused of falling into a therapeutic fallacy (*therapeutic misconception*) for having unjustified therapeutic expectations and for having misunderstood the information about implied risk in their participation[22]. It is forgotten, however, that frequently it is the researcher who hints for uncertain or non-existent medical benefits to better convince individuals to take part in a study.

To this regard, the concept of therapeutic fallacy – *therapeutic misconception* – has been described, and which is often induced by the researcher's informative speech. From the moment that a patient enters in a non-therapeutic trial, he will undergo possible unwanted effects even though it does not mean any medical benefit, in such way that the pondering benefit/risk becomes absurd and measurable when the numerator is zero.

The other argument to subtract the intention to benefit recruited patients for non-therapeutic researches supports that all knowledge is of social use and base for the progress of medicine. It is, then, citizen's duty to contribute to these common good processes: *the difference of clinic medicine, the risks/benefit estimate of a clinic research implies pondering net risks to individual subjects … related to the social benefits that flow from the generation of biomedical knowledge*[23]. The validity of this argument is refuted by the huge redundancy and non productivity of the large mass of biomedical researches carried out, many of them boosted by personal or corporative interests as it happens with redundant drugs researches that do not innovate in relation to the existing ones – *me too drugs*[16]. Other factors should not be forgotten, such as the huge academic pressure that incentivates research for institutional prestige reasons, work stability and academic career– *publish or perish*–, material stimuli and knowledge market practiced by editors, congress promotors, event agents, and lecturers.

Risks without benefits – objectiveness

Clinical studies undertaking has become ever more frequent as well as molecular research in people with illness where it is recognized that there will not be any medical benefit for recruited individuals, trying to reach objectiveness in risks so they lose their unpredictable feature and to seem more harmless. This trend is already noticed in the *Belmont Report*, which recommends *the idea to emulate as much as possible non-arbitrary systematic analysis of risks and benefits*, so *the procedure leads to a more rigorous and accurate evaluation of researches, inasmuch as the communication among members of Committees and researchers be less susceptible to misinterpretations, disinformation and conflicting opinions*[24]. This proposal is useful to eliminate unacceptable risks situations and to make transparent predictable benefits and risks, but it is notorious that the issue seems to be solved between researchers and committees, without considering its presentation to people who will provide the informed consent.

Research Bioethics Committees have among their tasks that of detecting and clarifying as objectively as eventually posible unwanted effects of the trial, including the caution of refuting procedures that include unacceptable risks due to their magnitude or

frequence, as well as to inspect material incentives that test research subjects into accepting higher risks. It is particularly difficult the task of objectively pondering the risks of a study that by definition are unknown, above all in clinical or experimental procedures that interfere with biological processes, being undispensable that the evaluating Committee acts prudently and with live concern to protect research subjects.

Some researchers cricticize Committees' caution as an oficial interference in issues that should be decided from the autonomy of competent individuals who, having been suitably informed, would decide based on the liberal principle called *limited voluntarism* if presented risks, in their view, deserve to be accepted and, consequently, assuming responsibility for unwanted effect that may occur. To interfere in their, altruists, monetary, selfish motives or of any other type would be, from this perspective, an unacceptable paternalism, a reasoning that liberates unduly the researcher accountability for risks that cause damage in consequence of the study, and suggests to Committee to not evaluate risks that research subject would voluntarily accepts[25]. This disqualification of Committees is very irresponsible when the same researchers recognize difficulties and limitations to undertake informed consent with people whose culture and language are different from their own. It is precisely in these scenarios that Committees should go to extremes in their protection roles.

The attempts to be objective about possible negative effects in intervened biological processes are very partial. It is necessary to consider that its perception is, at least, as important as the presumed objectiveness of a risk. The individual perception of risk has strong influence on people's behavior, pushing them into getting additional insurance, to enter with particular caution in situations that seem dangerous to them or to deny assuming unavoidable risks. Besides personal attitude, there is the social perception of risk as it happens usually with ecological issues and in face of eminence of epidemics. Informed consent procedures included in all research protocol wrongly assume that people are behind an ignorance veil as if there is not biographic, psychological, or contextual influence that surpasses the mere objective computation that evaluates risks. Medical or scientific agents that try to minimize risks emphasize on the remote probability of their occurrence in such manner that the subjective fears of the recruited are concentrated in the severity of resulting effect in case risks become real.

Risks minimization

There are, at least, three proposed rhetoric strategies, preferably used in recruiting research subject to take away severity of possible risks: a) inadequate information; b) comparison with risks from alien activities to the research, and c) typification as minimum risks.

Jesse Gelsinger's death dramatically illustrates deficiencies on information about risks [26]. The unexpected outcome of genes transfer trial in a 21 years old young man, asymptomatic carrier of a liver disease under study, he was not informed as a possible risk despite existing precedence from previous studies that pointed towards that possibility. Risks misinformation may be involuntary due to deficient communication or to insufficient previous studies; but it may result from a deliberate minimization of possible negative effects in order not to frighten off possible research subject. The researcher has the duty to inform his prospective subjects of the research in a complete, impartial, and personal way, instead of reducing IC into a document signing procedure. This aspect is important to stress how much Bioethics Committee may have been satisfied with risk protocol presentation but soon distorted by incomplete or biased submission of this information to facilitate obtaining voluntary consent from subjects.

The miminum risks concept initially introduced to apply in therapeutic clinical studies carried out with children who were not yet in conditions to evaluate risk or to make decisions about their participation. Although currently its use is proposed for many other types of researches in which informed consent is not considered as necessary or it is assumed to be unreachable [27].

Two forms define minimum risks: as the risk that every individual faces daily throughout his activities or as the risk that patients undergo due to their routine medical treatment. Both criteria are vague and insensible to people's individuality and to contextual variables, in addition to hiding uncertainties and possible higher risks inherent to every biomedical research[21,28].

The attempt to giver objectiveness to minimum risks by comparing those to diverse situations to those of the research, such as for example the organs donation, is inadequate because the analogy fails. The living donor submits himself to a risk with the certainty of the benefits that his donation becomes possible as the sole alternative for the receptor to survive or to be free from the severe harshness of the dialysis machine. Comparatively, recruiting for a non-therapeutic study hardly can intend to justify itself with presumed and hypothetic undetermined social benefits presented since a large proportion of the biomedical research have stakeholders who are alien to public good. None of these suggestions for taking away the severity of possible risks dissipates uncertainties and eventual deleterious consequences to be part in a study that do not benefit the patient. In honor of medical protection that they are entitle to, *non-therapeutic studies should not recruit ill people, a prohibition that achieves its maximum requirements when the banned subjects in research are not mentally competent.*

The precautionary principle

Another strategy to take risks to an innocuous uncertainty is to apply the precautionary principle, mainly in community studies that looks for impersonal authorization for research. Precaution consisting in proposing a program implementation– introduction of a drug, an agrochemical, an insufficiently studied vaccine – even when possible risks are neither well known nor have been evaluated, but that are presumably reasonable and justified by supposed benefits of the action. The precautionary approach in more pragmatic and stakeholders tan scientific terms shelters the danger of not questioning exhaustively potential unwanted effects and the under-notification of detected risks. The haste to introduce a product in the market relies upon a supposed precaution, more rhetorical tan real, to avoid risks. This explains the withdraw of drugs from the market that resulted as toxic, the need to stop clinical studies in advance, the catastrophic appearance of massive deleterious effects, such as Thalidomide.

The suggestion to apply a harsh precautionary version when potential risks are *particularly bad*, and to be more tolerant in face of less severe risks, just continues uncertainties and undefinition that affect the precautionary principle[29,30].

The less quantifiable are the effects of the proposal, more susceptible is precaution to influences of power, to productive forces minimizing risks and exaggerating benefits, the affected community insisting in eliminating residual effects, which ends up being a conflict of power and ideology.

It is worrisome that ethical standards and academic bioethics charged with the topic tend to justify these several strategies to mitigate risks perception even when many researches are markedly prone in producing unexpected deleterious effects. The criterion of explaining what is ethically permissible in these issues still is respectable, and that it was formulated 40 years ago as the Papworth principle, consisting of appealing to common sense and to the ethics traditional Golden Rule of questioning researcher if he would be prone in applying these recruiting rhetorics to his own children[31].

Risks to *vulerable* people

Cioms much inadequate definition describing vulnerable people as *those absolutely or relatively incapable to protect their own interests*, reflects the assertion that *the US regulatory system describes vulnerability as the absence or presumed reduced capacity to consent*[32]. By denying mental competence in such arbitrary way, doors are open for a manipulative persuasion, coercive at times, by researchers toward those so-called

vulnerables indivíduals and communities. This actitude, more colonialist than paternalist, should be detected in studies promoted by corporations and institutions that look into the convinience of moving their trials to less developed countries. Among the causes for vulnerability, it mentions those *politically not empowered members of communities without knowledge of modern medical concepts … those economically at disadvantage*[33]. These descriptions are applied to people and communities from less developed nations, which in researcher's perspective will be catalogued as vulnerable and non-autonomous according to Cioms rationale, been submitted to risks and rigor of a study without a suitable instrument that mediates voluntary consent.

All these arguments are powerful reasons to reinforce the work of the Bioethics Committees in Research in host countries and to not trust in the ethical evaluations that come along with protocols prepared in sponsors' country. These local Committees should guard with all rigor that researches with human beings are cautious in reducing risks, and they should persist in protecting research subjects with information and requirements even when rigor of procedures bother researchers and sponsors, and may affect their interests[34]. The Hypocrites maxim of *primum non nocere* should be recuperated and respected for invasive procedures and potential risks that are part of the contemporary biomedical practice and research.

Final considerations

The current text take a decided stand in defense of the research subjects, mainly if they are patients or impaired people, who are increasingly recruited for reseaches moving to countries with scarce socioeconomic development. It is evident that researchers see efforts to protect research subjects as a constraint for the free development of science. However, they, far from been deplorable, are an ethical requirement to maintain and to strengthen, mainly when it is considered that the bulk of clinical studies carried out is redundant, and they abide to strategies from the pharmaceutical industry striving for market niches or to get/renew patents, developing drugs that will leave interesting use. Corporate and academic interests prevail over dedication in solving social needs and therapeutical gap[35]. The search for therapeutical and preventive solutions for illnesses that epidemiologically plague population whose insolvence does not point to promising markets remain unattended, an unbalance known as the gap 90:10, according to which the majority of research funds are invested to study a scarce number of medical problems that concern more develop countries.

Those researches that are novelties and creative should also be accurately evaluated, as they are carried out in molecular and sub molecular systems which afect multiple biological processes and in a way that may not be clarified possibly with menopausal determinism approach but require to resorting at the chaotic or complex determinism that shelters an immeasurable amount of unpredictable effects.

Bioethics National Commissions that are been established in many nations should include among their functions the careful surveillance of recruited people integrity[36], taking into consideration that biomedical research is undertaken increasingly by commercial institutions, the *Contract Research Organizations* (CRO), that are evaluated by private Committees which target profit and displaced to less developed nations where supposedly ethical requirements are much more lax. The hosting countries should survey with special care the undue application of research double ethical standards that provide a maximum or *inspirational* ethics in sponsoring nations, which only grants a pragmatic, contextual, or situational ethics to poor nations that host imported studies[37]. It is necessary also to control the work of many Institutional Research Bioethics Committees, which are surpassed in their effort by the growing quantity of studies to be evaluated. The topic of risks in clinical and research procedures should keep its proeminence in biomedical research, protecting utmost involved people.

Resumen

Bioética de riesgos biomédicos

El consentimiento informado (CI) para procedimientos médicos o estudios clínicos se fundamenta en ponderar beneficios versus riesgos. Procedimientos terapéuticos e investigaciones biomédicas de avanzada pueden albergar riesgos de envergadura, mientras los beneficios para participantes se vuelven marginales o inexistentes, sobre todo en estudios no terapéuticos. Para facilitar el reclutamiento de participantes, se ha propuesto enfatizar beneficios médicos inespecíficos o apelar vagamente al bien común que sería fomentado, lo que estimula falsa expectativas terapéuticas. Los riesgos son informados en forma incompleta, mitigando magnitud o probabilidad de efectos negativos, y recurriendo a la doctrina de riesgos mínimos para reclutar tanto personas autónomas como a los de competencia mental reducida. Las barreras culturales y socioeconómicas entre investigadores y población de naciones pobres que hospedan los estudios, han creado la categoría de *vulnerables* definida como la incapacidad de cuidar los propios intereses, indebidamente estableciendo relaciones paternalistas que lindan en lo colonial.

Los comités de ética deben extremar sus evaluaciones para proteger a las personas que son incorporadas a procedimientos de beneficios inciertos y riesgos desconocidos o mayores de los informados.

Palabras-clave: Consentimiento informado. Ensayos clínicos como asunto. Ética. Investigación biomédica. Riesgo.

Abstract

Bioethics of biomedical risks

Informed consent for medical procedures and research protocols is based on a benefit/risk evaluation. Sophisticated therapies and front-line investigations, especially if non therapeutic, often have only marginal or no benefits, and yet may entail considerable risks. To facilitate recruitment of patients and research subjects, a therapeutic misconception is often created by vaguely promising non specific medical benefits and appealing to support of the common well. Incomplete information of risks, and the rhetoric of minimal risks are employed to recruit competent patients and those with impaired capacity of decision. Cultural and socioeconomic barriers between researchers and the population from poor host nations have promoted the idea of *vulnerability* defined as the incapacity to look after one's own interests, thus justifying paternalistic attitudes reminiscent of colonialism. Ethics committees are called upon to protect patients and research subjects by stringently evaluating procedures that are of uncertain benefit and insufficiently informed or unknown risks.

Key words: Informed consent. Clinical trials as topic. Ethics. Biomedical research. Risk.

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