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Ethics committees and mental health[☆]

Carlos Enrique Yepes Delgado^{a,b,*}, Andrea Ocampo Montoya^a

^a Facultad de Medicina de la Universidad de Antioquia, Medellín, Colombia

^b Unidad de Investigaciones, Hospital Pablo Tobón Uribe, Medellín, Colombia



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ABSTRACT

Although research processes are covered by the objectivity of science, they are still influenced by the interests of those who conduct them. This is why high level committees have been tasked with defining the scope of the studies and performing a thorough assessment of them, since these imply great dilemmas. This premise leads to the emergence of Ethics Committees, where liaison psychiatry has an important place due to its communication abilities and knowledge of the human behaviour. This paper attempts to provide some observations to take into account when discussing the link between ethics and mental health. In this work, the authors approach the question of ethics committees and the importance that psychiatrist performance has within them. This is done through a review of relevant papers on the subject. A detailed description on research ethics is provided in terms of justification, purpose and duties. Likewise, emphasis is placed on each of the areas in which psychiatrists are involved and bear great responsibilities in the medical decision-making process. Similarly, this description also includes the moment in which participants give their informed consent when taking part in medical research. Finally, we conclude that there are several questions regarding the relevance given to these committees in the methodological and ethical assessment of research projects. This in turn implies greater effort in the search for a culture of quality which highlights the emphasis on research subjects.

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Comités de ética y salud mental

RESUMEN

Los procesos de investigación, aunque están comprendidos en la objetividad de la ciencia, no dejan de estar permeados por los intereses propios de quienes los ejecutan. Por eso se han destinado comisiones de alto nivel para delimitar el alcance de los estudios y hacer un examen riguroso por los grandes dilemas que acarrearán. A partir de esta premisa surgen los

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* Corresponding author.

E-mail address: caenyede@gmail.com (C.E. Yepes Delgado).

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comités de ética, en los cuales la psiquiatría de enlace ha ocupado importantes puestos, por sus habilidades en comunicación y conocimiento del comportamiento humano.

El presente artículo pretende aportar algunas observaciones que tener en cuenta en la relación existente entre la ética y la salud mental, al abordar el escenario de los comités de ética y la importancia del desempeño de los psiquiatras en ellos, mediante la revisión de artículos clave sobre el tema. Se da una descripción detallada de la ética de la investigación, en cuanto a justificación, propósitos y deberes, haciendo énfasis en cada una de las áreas en que el psiquiatra se ve envuelto con grandes responsabilidades en el ejercicio de la toma de decisiones médicas hasta el aval en el consentimiento informado de aquellos que participan en las investigaciones médicas. Finalmente, se concluye que existen varios interrogantes respecto a la relevancia que se ha dado a estos comités en la evaluación metodológica y ética de proyectos de investigación, lo que supone mayores esfuerzos en busca de una cultura de la calidad que realce el énfasis en el sujeto de investigación.

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Introduction

The desire for knowledge tends to be accepted and valued socially as a routine everyday process in humans. In addition to desiring and promoting the pursuit of knowledge, we even assign recognition to those who develop it and encourage research in various areas of society. The fact that it is a natural desire of humans precisely exposes us to be permeated by multiple interests, in some cases alien to the conscious will of the person. Objectivity as a reiterated paradigm that sustains the classic conception of science has not been able to purge the investigative task of the non-rational components inherent to the subject who investigates, despite the enormous efforts of some scientists to cover up multiple features of subjectivity or political choice.¹

Both the motivation and the scope of the research, arising from human freedom for the right and the duty to know, have individual and collective implications, as science has gone from being a matter of exclusive interest of the scientific communities to having implications in society as a whole. Thus, the public policies that define research reflect the priority given to it in the different countries around the world, in many cases assigning high-level commissions to delimit the scope of the studies, and these guidelines appear subject to the interests that reflect implementation of the policy, expressed in legislative acts of various kinds. The foregoing introduces multiple tensions into the conducting of research, which far exceed the merely cognitive scope and overlap with values such as justice, welfare and freedom, among others.²

In addition to the recognition biomedical sciences deserve thanks to the impact on the protection of people's health, not only in the physical and social, but also psychological, fields, some of the practices associated with research require rigorous examination because of the great dilemmas they give rise to. Such examination involves reviewing the research processes, the responsibility of its purpose and the validity and acceptability of the media, as well as verifying the legitimacy of those who define these practices,³ and even more so if they are associated with people's mental health. In order to meet these objectives, the creation of committees made up of people with extensive knowledge about ethics has become

essential. At the same time, in the search for communicative, educational, cultural relations and teamwork skills,⁴ a select group of psychiatrists has been necessarily involved in the committees in order to successfully give continuity to these processes.

What is an ethics committee?

According to the United Nations Educational, Scientific and Cultural Organisation (UNESCO), a bioethics committee "is responsible for systematically and continuously addressing the ethical dimension of (a) medical and health sciences; (b) biological sciences, and (c) innovative health policies. The term "bioethics committee" denotes a group of people who come together to address issues that are not simply factual, but are also profoundly normative". This is the way in which particular individual and social values are questioned and studied with rigour, and is equivalent to assessing our own behaviour and that of others. Although initially they were created to support doctors in behavioural decisions in moral dilemmas, today they are a requirement for the assessment of biomedical research projects in humans and they advise professional associations and those who formulate public policies. Healthcare professionals who deal with mental health have played a particularly important role on these committees, ranging from educational functions on elements for mental assessment and communication and organisational skills for ethical reflection, through the development of policies related to decisive and controversial treatment, to the approach to complicated cases in which emotions and moral judgements are factors inseparable from the ethical evaluation.⁵ There are currently four recognised types of ethics committees: policy-making and/or advisory bioethics committees (PMC); health-professional association committees (HPA); healthcare/hospital ethics committees (HEC); and research ethics committees (REC).⁶

According to the Colombian Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) [National Institute for Food and Drug Surveillance], the research ethics committee is the organisation responsible for guaranteeing the protection of the rights, safety and well-being of the humans involved in a clinical study through the review, approval and

constant monitoring of the research project, the amendments and the informed consent of the study participants, among other related documents. Such evaluation should always be aimed at preserving the integrity of the participant in the study, over and above the feasibility of carrying out a research study in a centre or institution providing healthcare services. For that reason, the ethics committee is the highest authority in the research centre for maintaining the integrity of research participants.⁷

In addition to the bioethical problems that arise in research, relationships with the participants are a key element for impeccable work in studies. This is where psychiatry comes in, and specifically liaison psychiatry, taking important positions in the discussion tables, insofar as it is recognised as the most humanistic form of the medical sciences. It has broad familiarity with many of the clinical problems faced by the committees with well-established skills in working on ethical issues, in terms of ease of communication, knowledge of human behaviour and assessment of the mental capacity of the participants. Psychosomatic medicine is in the perfect position to exercise leadership in ethics committees, thanks to its experience and proximity in the application of ethical principles.⁸

Rationale for ethical assessment

The greatest challenge facing research ethics in the world is the application of universal ethical principles (respect for persons, beneficence and justice) in different cultural contexts, which involve multiple health systems which all develop their own parameters for measuring and evaluating care. Those principles did not come out of nowhere. Terrible events in the history of humanity in relation to subjecting people to the risks of research not guided by good clinical practices means that today we have an arsenal of international guidelines that aim to shield society from the imminent risk of research without responsibility. These include, among others, the Nuremberg Code, the Declaration of Helsinki from the 1964 World Medical Assembly⁹ and the Belmont Report. International ethical guidelines for biomedical research in humans prepared by the Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation, aware of their limitations in terms of responding to all questions of moral order raised when conducting research, establish that ethical standards must be universally accepted in accordance with local cultural values in non-substantive aspects. The aim is to promote biomedical research with a high ethical and scientific level by guiding researchers, sponsors and ethics committees about the standards expected in the formulation, conduct and follow-up of studies.¹⁰

Among the universal ethical principles, one of the first is respect for persons, which includes respect for the autonomy of those who have full capacity for deliberation and protection against harm or abuse for persons with any degree of vulnerability or physical, mental or social dependence. Beneficence requires maximum benefit and minimum harm, which implies weighing the reasonableness of the risks according to the expected benefit, within the framework of valid research designs and the appropriate responsible personnel for the conduct of the studies. The prohibition of causing deliberate

harm is a premise of beneficence that is usually expressed as an independent principle of non-maleficence. Lastly, justice, from a perspective of distributive justice, requires morally correct treatment of the subjects, which implies equitably distributing the burdens and benefits among the participants in the research, taking into account age, gender, socioeconomic status, culture, ethnic considerations and psychological traits. This last principle has direct consequences both for people in vulnerable conditions, who require specific special protection, and for populations in low-income regions and countries to ensure that after the research their health situation improves or at least does not worsen.¹⁰ Precisely with the aim of protecting the vulnerable population exposed to participate in research, the CIOMS produced an updated version, which has just recently come into force.¹¹

In psychiatric ethics, the principle of respect for autonomy is the most discussed. A patient's autonomy is compromised in cases in which they are externally coerced or have reduced mental faculties in understanding, intentionality or ability to make voluntary decisions. The psychiatrist's assessment is therefore directed at legitimising the informed consent. Both autonomy and informed consent are expressions which, since the 1970s, account for the reduction in the conception of bioethics prevalent until then, on being applied to the biomedical field from the Anglo-Saxon individualistic perspective, which is based on the autonomy of social subjects linked to the principles of beneficence and non-maleficence, but subordinating the issue of justice in collective terms to a second plane. The over-dimensioning of the autonomy of North American bioethics strengthened an individualistic and singular vision of the conflicts expressed in a large multinational industry for informed consent for subjects receiving medical treatment who are the subject of research, which starts from uncritically considering all persons autonomous, regardless of their socioeconomic level and their schooling.¹²

In relation to autonomy, it is worth asking who really decides in the scenario of medicine and therapeutic interventions. Perhaps a sufficiently informed person? How aware is the researcher really of the risks that the other person runs? It tends to be based on statistics and evidence that often nobody even bothers to evaluate critically. Perhaps they are presumed to be unquestionable because they come from some authority of the same discipline and/or from large pharmaceutical industries that have been doing research in the field for many years, and they are often the ones who provide therapeutic alternatives for the same patients. As patients, we could reasonably ask our doctor how many people they have previously exposed to the risk in question and what the outcomes were, but because of a matter of "natural" subordination and having to trust in the end, while even to suspect that your doctor is not up to the task of meeting your needs would be terrifying, we simply subordinate our decision and we have to trust.

With that reflection, we need to stop for a moment to explore some reference points in relation to the very concept of autonomy, as this has to be understood from the perspective of human vulnerability, which is ontological, ethical, social, spiritual, physical and cultural. Autonomy cannot be therefore considered absolute under any circumstances, but is built in more complex degrees that can include absence of external coercion, freedom of decision, choice based on rationality and

the recognition and assumption of moral values. Once recognising the ambiguity of the human condition, the above point does not prevent us from being able to differentiate between autonomy and the autonomous action. That becomes evident when an autonomous person is heteronomous in some actions and vice versa, meaning that human autonomy is never purely autonomous, especially when confronted with great social determinants and symbolic traditions in which it is immersed.¹³ This applies not only to the people exposed to therapeutic and research interventions, but also to the healthcare personnel themselves.

Hence the appeal to healthcare personnel, regardless of the quantity and quality of the information they think they have, to avoid making the decision for the other person. Among other reasons, this is because of the amount of undeclared interests that tend to accompany the daily process of making decisions, added to the fact that, when people think of themselves as possessor of some truth, they automatically decide to impose it on others. That last point takes on special meaning in the mental health setting. With great reason it can be claimed that there are "technical criteria" to label as mentally ill someone assessed by a professional using pre-established nosology that classifies various symptoms as expressions of pathological processes, the response to which is usually drug therapy; a situation which can have significant consequences.

Non-maleficence takes a prominent role over autonomy, and beyond the interests of researchers, the best possible outcome for the patient must prevail, especially in cases where their ability to deliberate is impaired. This precise scenario could create tension between the psychiatry and bioethics approaches, as they operate with different concepts of capacity. While in psychiatry the aim is to determine whether or not the person is competent, in bioethics, the important thing is their decision-making capacity; ideally this situation should represent an opportunity to seek synergy in the combined set of arguments constructed from the two distinct positions.¹⁴

Nature of ethics committees

Ethics committees may have a national or international scope of influence. In each country, institutions, towns or regions may have ethics committees and there may even be one which covers the entire territory, as defined in the policies of each nation, and will take into account their multidisciplinary, multi-sector and pluralistic nature to achieve a comprehensive evaluation of the projects.¹⁵ Due to the characteristics and the degree of responsibility that the ethics committees have, they must be competent and optimise their administrative processes, and for that they require financial support. A decentralised evaluation of the research, with unified guidelines by country and information systems which allow networks to be created and establish review by levels between committees, can generate more efficient ethical assessment systems with greater coverage according to the needs of each region, and thus contribute to the highest ethical and scientific quality of biomedical research.¹⁰

Within the multidisciplinary nature of the composition of ethics committees, some authors place great emphasis on the importance of a psychiatric clinical perspective and the fact that liaison psychiatry is well positioned to assume the role

of ethicist regarding the choice of treatment and the assessment of mental capacity for medical decision-making. Over the last 20 or 30 years, with the recognition of the importance of ethical issues, this work has been relegated to ethical consultants, as many of the tasks were found to be overlapping in numerous domains. However, the clinical and administrative responsibility remains with the psychiatrist, in particular the speciality of psychosomatic medicine which many of them practice.¹⁶

Purpose, responsibilities and composition of ethics committees

The purpose of an ethics committee when evaluating biomedical research is to look after the safety and well-being of all participants. The objectives of the research cannot be above the health and well-being of the subjects participating in it, and mental health plays a crucial role, as combining the responsibility to represent the interests of potential participants while taking into account the needs of researchers and the demands of regulatory and control bodies becomes a permanent challenge for ethics committees.¹⁵

The basic responsibilities of ethics evaluation committees and the role that the psychiatrist as expert can have are:

- To determine that all proposed interventions, particularly the administration of drugs and vaccines or the use of medical devices or procedures to be developed, are acceptably safe to be performed on humans, or to verify that another body of competent experts has so determined. In this aspect, psychiatrists have much to contribute from their knowledge of possible harmful effects for the mental health of people involved in research or exposed to certain medications and interventions.
- To determine that the proposed research is scientifically valid or to verify that another body of competent experts has determined it so. Providing psychiatrists with solid training in basic aspects of epidemiology, evidence-based medicine and critical reading will allow them to fully comply with this responsibility.
- To ensure that all ethical concerns arising from a protocol are satisfactorily resolved, both in principles and in practice. The psychiatrist's clinical experience and, as part of that, the ethical dilemmas they deal with on a daily basis help prepare them to handle such situations.
- To consider the qualifications of the researchers, including their research training, and the conditions of the place where the research will be carried out in order to ensure the safe conduct of the trial. A rigorous analysis of the context of the study and its participants from the experience of the clinician who deals with mental health could anticipate preventable difficulties in the research.
- To keep records of decisions and take measures to monitor the progress of research projects.⁷ The accompaniment that can be provided not only to the project, but also to the participants in it, in order to identify any changes in the sensitive aspects of the behaviour at an early stage would be an important contribution from the mental health experts.

In order to function effectively, ethics committees must establish their own regulations, which reflect their code of conduct and their conflict of interests management policy, in light of compliance with good clinical practice standards and, in Colombia, the guidelines of the INVIMA (Guide for the evaluation and monitoring of research protocols, Code: ASS-RSA-GU039 Version: 02 Date issued: 05/05/2016 and Guide for research ethics committees Code: ASS-RSA-GU040 Version: 00 Date issued: 01/04/2015), and the norms that now govern aspects related to informed consent and the level of risk of research (Resolution 8430 of 1993) and good clinical practices in Colombia (Resolution 2378 of 2008), in addition to the guidelines for correct completion of the medical records: Resolution 1995 of 1999. Along the same lines, the committees must guarantee security and confidentiality in the administration of documentation, both physical and magnetic, and make public the procedures that allow the authority that governs them and the functions and characteristics of their members to be seen as transparent and acting in consonance. In relation to the national standards on hospital ethics committees, the country has Resolution 13437 of 1991, which establishes these committees, and the Ministry of Health of Colombia has adopted the "Ten Commandments" of patients' rights.

The structure of the ethics committees should guarantee a comprehensive and competent evaluation of the ethical and scientific requirements, for which its members need to represent different medical and non-medical disciplines, as well as sectors with multiple interests, including those of the community, and balanced by gender and age.¹⁵ Ethics committees must define in their regulations the criteria for election and replacement of their members, as well as the positions and responsibilities, the minimum number to deliberate and decide, the periodicity of their meetings and the training schedule according to their requirements.⁶ If necessary, independent consultants can be brought in who fulfil specific technical and assessment functions, to ensure that the quality of their work is not affected by the demand for projects to assess⁷; here, psychiatrists could actively participate as experts in the validity of shared deliberation, established by means of adequate information, motivation, consensus and evaluation of the consensual decision, as well as the legitimisation of coercion when necessary.¹⁷ It is also necessary for the members of the ethics committees to sign confidentiality agreements regarding what was discussed at the meetings and to keep a record of the different positions and discussion stemming from the ethical dilemmas analysed, as well as the final ruling that reflects and expresses a preference for consensus.¹⁸

In relation to the profile of the members of the ethics committee, it is advisable to have personnel who meet the following characteristics: medical professional; bioethics training; training in social sciences; knowledge in research methodology, epidemiology or statistics; experience in clinical research; legal professional; pharmaceutical chemist; priest or chaplain. Whoever represents the community and the participants in the studies should have a critical attitude and be able to defend the rights of those they are representing, ideally from having been a research subject themselves.¹⁹ In terms of the clinical staff, we should highlight the role that mental health experts fulfil because they have a much more reflective

approach to problem solving and have a greater capacity to work cooperatively, interest in ethics, tolerance for ambiguous reasons and ability to work outside a scientific frame of reference.⁵

Risk assessment in clinical research

Ethical suitability depends on the ability to protect research participants from excess risks.¹⁹ In view of the lack of a systematic framework for risk assessment in research, both researchers and funders and even review boards rely almost exclusively on their own judgements from intuition, which are plagued by well-documented biases. This situation can lead to the risk of research subjects not being protected; if we look in detail at possible mental health conditions, the problem would undoubtedly be even greater. A method called systematic risk assessment in research has been proposed to help deal with this problem. The method measures the risks of research interventions comparing them with those of other known activities which have been considered acceptable. Through four steps, the method aims to identify the possible harm that the proposed intervention could cause, classify the magnitude of the potential harm on a seven-level scale, estimate the likelihood of each possible harm and compare it with the likelihood of harm of the same magnitude that occurs as a product of the appropriate comparison activity. The experience psychiatrists have in the application of diagnostic scales could mean they have the preparation to carry out this assessment properly. This minimises the influence of biases in the assessment of risks in research and better protects participants from excess risks.²⁰

What do ethics do to clinical research?

From the international normative theoretical framework on universal ethical standards, there are certain requirements for making clinical research ethical: the value, referring to the scientific, clinical or social importance of the research, whether for providing improvements in the physical and mental health of individuals or communities, or for the contribution the research makes in terms of knowledge; the scientific validity supported in that the proposed study is rigorously methodological; the equitable selection of potential subjects in terms of distribution of burdens and benefits; to establish a favourable relationship between risk and benefit in the context of standard clinical practice and the research protocol, minimising risks and increasing potential benefits, so that these individual benefits and the knowledge acquired by society outweigh the risks; independent assessment; informed consent, which must guarantee that individuals have been informed about the research and that they voluntarily gave authorisation for their participation; and protection of the privacy of the subjects recruited; that they must have the opportunity to withdraw; and to supervise their welfare during the study.^{20,21}

Education of the committees

The continuous training and qualification of the ethics committee members, besides being a necessity, is an obligation for the level of responsibility that accompanies the exercise of

their duties. All new members must therefore have the necessary induction and initial training. Subsequently, there should be a training programme on substantive aspects of ethics and other related issues which allow the work done to be qualified, enrich the quality of the discussions in the committee and legitimise the decisions made.^{15,22}

International guidelines propose taking into account issues such as introduction to philosophy, assessment of research designs, bioethics, research ethics, informed consent, public health, human rights, culture, anthropology and sociology, human groups in conditions of vulnerability in which the psychic aspects have great relevance, etc.²² They also place great emphasis on learning in psychosomatic medicine, in order to obtain greater knowledge of ethical issues, moral reasoning and organisation guidelines, as well as skills for identifying the nature of uncertainty in decision-making.⁸ Once the training programmes are underway, the committees are expected to initiate evaluation and self-assessment processes, to the point that they can even report their actions publicly and thus gain legitimacy both institutionally and socially.

Aspects on opinions and monitoring

The opportunity in the response that the ethics committee gives to requests for research protocols is a key factor, not only of competitiveness in the modern world, but also of social responsibility, in view of the impact that research can have. It goes without saying that the quality of the assessment is more important than the haste, but if the dynamics of the committee enable these two elements to be harmonised responsibly, the committee becomes more efficient and effective.

The communication issued by the ethics committee at the end of the session must contain the date, the site and the name of the committee that made the decision, and make an explicit statement of the decision made, which may be to approve with or without recommendations, condition approval to comply with ethical or scientific requirements or reject the research project.

In the case of a conditional failure, the committee must be very particular about ensuring compliance with the requirements before issuing the acceptance and the start of the study. In case of rejection, the reasons that led to this decision must be detailed.¹⁵ In case of approval, researchers are advised to keep the ethics committee's communication, as it is usually a requirement demanded by the editors of scientific journals for publication.

It is important to recognise that the work and responsibility of the ethics committee when approving a protocol is just beginning, as the committee must carry out and document the monitoring of the accepted protocols until their completion. To this end, it is essential to establish clear communication mechanisms with all those involved in the project that will enable responses and decisions to be made effectively regarding amendments to the initial protocol, in order to protect the integrity of the study subjects, with emphasis on the aspects related to the mental health of the participants, which also includes carrying out fieldwork at any time to verify the recruitment conditions offered in the project, the application of the proposed interventions, etc.

Informed consent in special situations

Informed consent has become the foundation of any scientific research recognised as ethical. It includes recognition of clear information provided by the research team to the participant in a study, which is preceded by motivation, consensus and assessment to ensure adequate deliberation that establishes full knowledge of the procedures and risks to which the participant is exposed. Before it can be approved, basic issues of the voluntary nature, validity and authenticity of capacity must be clarified.⁸

For the purposes of informed consent, it sounds very simple to explain the advantages and risks to which people will be exposed. However, although this would be true in the case of calm, reasonable people with sufficient information regarding a minor matter that does not affect their safety, such as buying a utensil or a dress, the reality of a research study scenario is quite different. Uncertainty and fear often accompany our decision processes, our doubts about the safety of the intervention offered, and even the suitability of the person offering it. This issue comes before what then takes over, attributing superhuman skills to the therapist. Not to mention the undeclared uncertainty of the person offering the therapeutic alternative, who tends to present themselves as full of confidence, at the risk of losing all credit and trust.

It is often assumed that informed consent forms are written in terms that are intelligible to those being invited to participate in the intervention. This is something that should be absolutely guaranteed by ethics committees, but in practice, when faced with a string of technical terms that make no sense in the first few paragraphs of a long text, particularly in the case of randomised clinical trials, it is not uncommon for the reader to end up feeling consciously and unconsciously under pressure from the treating doctor, and from themselves, to sign the form even without reading it completely or fully understanding the implications of the commitment they are taking on.

Talking about informed consent necessarily requires appropriation of that specific issue of relationships between human beings we call communication, which includes exchanges with reciprocal participation and understanding. Effective communication is necessarily linked to language as a particular vocabulary that allows us to express ideas, feelings and behaviour and enables better argumentation from a perspective of greater rationality and coherence.¹²

The conscious informed consent of an individual can be affected by a series of factors that clearly reduce autonomy, among which are compulsion, whether internal (neurotic impulses, obsessions, inhibitions and disabilities) or external (external risks or threats), and ignorance or wrong beliefs. When reviewing the literature in greater detail, we find that the limitations on autonomy can be expressed in different ways, such as inability to communicate a choice, understand a situation, understand information received, offer reasons which are rational and also weigh up the risk/benefit ratio, which ultimately results in an inability to make a reasonable decision.¹³

It is therefore obvious that psychiatric patients are at a disadvantage in view of the fact that their reduced decision-making capacity limits their autonomy. It is common to find

this limitation even leading to the deprivation of liberty or use of coercion, but this cannot mean that psychiatric patients may be used as research subjects, unless it is demonstrated that the benefits outweigh the risks.²³ In such cases, an ethics committee for mental healthcare recommends a common ideal of deliberation, consisting of information, motivation, consensus and assessment. It is recognised that there are situations that fall outside the traditional specifications which can be taken into consideration for "consented coercion"; for example, in the case where the person has little control over their own behaviour, if there is a threat of serious harm to integrity or there is a marked ratio between the harm and the coercion, in which case it must not exceed the scope of the harm.¹⁷ Good communication between the specialised psychiatric team and patients is a key factor for the correction of ethical problems that may arise as the study becomes imminent.²⁴

Challenges to be faced by ethics committees

There are significant differences in the way ethics committees work in different parts of the world. In northern countries, meetings are often held more than once a month, while in southern countries they tend to be held three times a year.⁶ This situation raises questions about the number of projects received by the committees in developed countries, the amount of money dedicated to research, the human resources dedicated to the formulation and assessment of research projects, the technological development that allows work to be carried out more efficiently, the commitment and discipline of institutions and professionals in the constitution and working of research ethics committees, the capacity in place and the commitment to compliance with international standards in order to be a centre of reference in research and evaluation of projects, etc.

In Latin America, the limitations that many research ethics committees have regarding their ability to perform methodological and ethical evaluation of research projects becomes evident, and, if they do exist, they tend to have more experience in support for studies for the pharmaceutical industry and less in research in social sciences. It is common to find that the running of ethics committees is reduced to a bureaucratic burden or even for them to become power-wielding agencies, which are ignorant of the importance of being pluralistic and multidisciplinary and devalue social participation. Lack of training in aspects such as science, ethics, morals, law and politics frequently narrows the eyes of those who issue opinions on research projects.²⁰

Rodríguez Yunta in *Acta Bioethica*¹⁹ states that the majority of researchers do not understand or value ethical control, and nor is it clear that an attempt is being made to contribute to the social development of Latin America. There is a formal assessment process for research projects in many institutions and the committee only meets sporadically or on request and there is no clear differentiation between the hospital ethics committees and the research ethics committees. The ethics committees have little administrative and funding capacity. There is a belief in some institutions that international research protocols do not require local analysis, despite the fact that most of the protocols analysed are

external. Many of the members of the ethics committees are completely unaware of their role and need better training. The number of professionals qualified to evaluate research protocols is insufficient. The mechanisms of supervision and control for reporting adverse events are still deficient, not to mention those for mental health disorders. The norms in different countries relating to the ethical regulation of research on humans is still deficient, or not applied, and only in some countries are there national ethics committees that regulate and control the work of regional and institutional committees.

For all the above reasons, there is a clear urgency throughout Latin America to improve the quality and coverage of bioethics training both among healthcare professionals and those in other areas of knowledge, including researchers and members of institutional ethics committees, in order to improve their ability to respond to the enigmas and ethical dilemmas they are faced with when conducting research in humans. Fortunately, in Colombia, some institutions providing health services and their respective ethics committees have been making significant efforts to develop a systematic and more rigorous working environment. This is the product of continuous learning and the decision to move forward in a culture of quality and patient safety, with special emphasis on the research subject.

Conflicts of interest

The authors have no conflicts of interest to declare.

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