EDITORIAL

ON THE LIMITS OF ETHICS IN MEDICINE

AUTHORS:

Hisrch, Roberto y Carvallo, Héctor
Editores, RAMJ

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The earliest ethical guidelines were drawn up in 1900.
They came about because of the improper use of human experiments.
Today, science itself sometimes sets boundaries even before legislators see a need for them.
Our prosperity is based to a large degree on our curiosity.
It is thanks to this urge to find out new things that life expectancy has doubled in the last hundred years.
So does this mean that humanity would be well advised to give free rein to its thirst for knowledge and to set no limits to science?
Numerous abuses make it impossible to answer with a naïve 'yes'.
These abuses have played a role in the gradual development of a complex set of regulations that today erects boundaries first and foremost for clinical research.
After WW II, the USA filed lawsuits against the doctors responsible for the Nazi experiments, and this led in turn to the Nuremberg Code.
This ten-point document from 1947 stipulates that a subject's consent must be given without compulsion or deceit and that it can thereafter be withdrawn at any time.
It also demands that experiments must intend to deliver "fruitful results for the good of society". The principles defined in this Code were refined by the World Medical Association and included in the 'Declaration of Helsinki of 1964', which states that vulnerable groups such as children, prisoners or the poor, for example, are entitled to more specific protection.
Ethics is an understanding of the nature of conflicts arising from moral imperatives and how best we may deal with them.
Ethics in medical research deals with the conflicts of interest across various levels. Guidelines have been proposed for standardized ethical practice throughout the globe.
Some special ethical issues have particular relevance to psychiatric research arising primarily from the specific vulnerabilities of those with mental illness and the risks posed by some research methodologies.
Accordingly, sensitivity is required in the design of psychiatric research.
It is suggested that though the value of

published guidelines and the help that may be available from research ethics committees is quite great, the primary responsibility for maintaining high standards of practice in research rests with research workers themselves.

ABUSE OF RESEARCH INTERESTS

Proactive laws

So it seems that clinical research has had to go through a long, painful history to be able to determine what is ethically and legally permissible.

But in basic research, the interaction between science and legislation also follows two further patterns.

There are proactive laws, such as those that forbid the creation of hybrids between animals and humans or the breeding of human clones.

These laws are enacted even before researchers are in a position to carry out such experiments. Then there are cases where scientists set their own boundaries before the legislators even see a need for it.

As medical ethics has evolved over the past several decades, it has come to be regarded as a domain of applied ethics, that is, the application of a rationally based, philosophical theory to moral problems in health care.

But an array of difficulties arise in the attempt to apply general moral theories or norms to concrete problems, difficulties that expose the incompleteness and indeterminacy of philosophical moral theory.

The doubtful ability of applied ethics to be practically helpful has led to the development of two main competitors.

One is the attempt to reprise and rehabilitate the tradition of moral casuistry, which focuses on the analysis of specific cases rather than on the defense and application of theories and norms. The second is the search for moral insight and guidance in narratives or stories.

These alternatives suffer from some of the same difficulties that plague applied ethics, however. Another trend in medical ethics rejects the theoretical preoccupation of applied ethics in favour of contextualism—an insistence on situating moral problems in institutional and organizational structures and in social and cultural backgrounds. Social science investigations of medical ethics pay attention to the former, while feminist critiques of medical ethics are concerned with exposing and eradicating cultural biases against women. Contemporary work in medical ethics is diverse, but these manifold approaches hold out the promise of improving our understanding of morality as a truly practical enterprise.

THE FOUR SCIENTIFIC ETHICAL PRINCIPLES

Autonomy

Research must respect individuals' right to autonomy.

This means that research must respect people's right to make their own decisions – in accordance with their own values and beliefs.

Generally, the consideration for autonomy requires that capable adults to a large extent should have the opportunity to decide over their own lives.

The principle of autonomy thus demands that one does not manipulate others, for example, by providing them with incorrect information, or by withholding information that can be expected to influence their decisions.

This principle also requires that one does not pressure people, for example, by imposing costs on their choices, and that one does not encourage others to act against their best interests or values,

for example, by paying them to take very large risks. Participants in clinical trials must, therefore, give their consent before they can participate in scientific experiments.
Among other things, this means that participants must be sufficiently informed about any risks, inconveniences, and burdens associated with participating in the trial. It also means that participants must not be manipulated, pressured, or unduly encouraged to give consent.

BENEFICENCE

Research should promote the good.

This means, in a broad sense, that research should create sufficient value to outweigh any risks, inconveniences, or burdens associated with conducting the trial.
This applies to the purpose of conducting the trial, the likelihood of the project's success, the usefulness of the trial's results, and so on. Poor research is, at best, a waste of time and scarce resources.
At worst, it risks exposing trial participants to unnecessary risks.
However, it's worth noting that not all forms of benefits count in this context. For example, it is presumably a good thing for the research staff to be paid for conducting the trial, but such benefits do not count in the scientific-ethical assessment. In a scientific-ethical context, it is about the potential to benefit the individual participant's health (individual value) or more broadly about better understanding or treating health problems for the benefit of the broader society (social value).
In the context of scientific projects, it must be demonstrated that new questions are being addressed, that the design of an experiment is well-chosen in relation to the question being answered, that the project is practically feasible, that the researcher in charge is competent, and so on.
All this must ensure that the project has the potential to contribute relevant value for either the participants themselves or the broader society.

NON-MALEFICENCE

Research must not cause harm.

This means, broadly, that there are limits to the risks, inconveniences, and burdens that participants may be subjected to.
This applies even if a project has the potential to create significant value, and even if the project respects participants' autonomy in all respects.
The principle of non-maleficence is in some ways the opposite of the principle of beneficence.
But while the latter requires that there are certain things one must actively do, the principle of non-maleficence dictates that there are some things one must not do.
In a research context, this includes not involving unnecessarily many participants, not subjecting participants to indefensible risks, not carrying out unnecessary experimental procedures, not wasting participants' time, and so on.

JUSTICE

Research must be fair.

This broadly means that a reasonable distribution of the benefits and burdens arising from a scientific trial must be ensured, unnecessary inclusion of vulnerable populations should be avoided, and equal opportunities to participate in scientific trials should be secured.
Regarding the distribution of benefits and burdens, it should be ensured (all else being equal) that the trial population is the same as the treatment population. In other words, it should generally be ensured that the group bearing the health-related risks, inconveniences, and burdens of participating in the trial is also the group that could potentially benefit from the trial's implementation.
Thus, it is not only for scientific reasons but also for reasons of fairness that the trial population (all else being equal) coincides with the treatment group.

Following the above, it is crucial that members of so-called vulnerable populations are not unnecessarily included in trials.

EIt is also an important principle of fairness that the strongest shoulders bear the heaviest burdens and that special consideration is given to the least advantaged. If it is somehow possible to conduct the trial on other populations first, one should start there before beginning to include members of a vulnerable population.

Furthermore, the consideration of justice implies that participants should be compensated for their expenses to participate in a trial, such as additional transport costs or lost earnings. This is not only for the sake of a fair distribution of benefits and burdens but also in terms of equality regarding the opportunity to participate in scientific trials.

Finally, the principle of justice demands active efforts to enroll members of underrepresented groups in research projects so that all members of society can receive their fair share of the benefits of scientific trials.

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