İSTANBUL UNIVERSITY PRESS

darulfunun ilahiyat

darulfunun ilahiyat, 29(2): 417–424

http://ilahiyatjournal.istanbul.edu.tr

Submitted: December 3, 2018
Accepted: December 12, 2018

RESEARCH NOTE

Procedural Bioethics and Content or Substantive Bioethics

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Daniel Buchanan argued that bioethics has three main functions: identifying and defining existing ethical conflicts; providing systems or methods to think about new emerging ethical conflicts in the field of medicine; and helping scientists and physicians to make decisions[1]. More than 45 years after Buchanan´s article was published, the existence in hospitals of mechanisms such as healthcare ethics committees, institutional review boards for clinical research, and the increase in standard operating procedures, plans, and manuals for clinical research has increased significantly. In other words, there is a greater interest and demand for procedures, leaving aside questions related to the content and moral foundation of the decisions[2].

Interest towards the decision-making procedures in solving ethical conflicts has resulted in a bioethics concept defined by Pincoffs as quandary ethics. This focuses on finding solutions to conflicts by asking questions such as "What should I do?" or "What is correct?", leading to a significant reductionism: being moral simply means that you should be responsible for complying with a norm or an ethical principle[3]. Quandary ethics puts more emphasis on the rules and procedures, and less on the content, and increasingly it seems that bioethics is acquiring the same classification as quandary ethics. This reductionism in bioethics is evident under the procedural approach of bioethics or principalism[4]. As stated by Mark Siegler in 1985: "The central question that has occupied a generation of American bioethicists has been this: Procedurally, where should decision-

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2 Daniel Callahan, "Bioethics as a Discipline," *Hastings Center Studies* 1, no. 1 (1973): 68.

3 Nancy Kass, Liza Dawson and Nilsa Loyo-Berrios, "Ethical Oversight of Research in Developing Countries," *IRB Ethics & Human Research* 25, 2 (2003): 8.

4 Edmund L Pincoffs, "Quandary Ethics," *Mind* 80, 320 (1971): 567.

5 K. Danner Clouser and Bernard Gert, "A Critique of Principlism," *Journal of Medicine and Philosophy* 15, no. 2 (1990): 417-424.

making power reside — with the physician or with the patient? A quite different question, and one that has been of much greater concern to clinicians as ethicists, is this: What is the right and the good decision for this particular patient in these clinical circumstances? In bioethics literature, however, ideas of right and good decisions have often been subordinated to procedural standards."[6]

We are faced with two ways of understanding bioethics — the procedural approach focused on principles, and the content or substantive approach focused on virtues.

Procedural Bioethics

In the second half of the 20th century, the practice of medicine entered a stage where mistrust between physicians and patients became the predominant note. It was then that codes and declarations were formulated to achieve greater regulation of human experimentation and clinical research in order to protect patients' rights, including the Nuremberg Code (1947) or the Helsinki Declaration (1964).

- Between the Sixties and Eighties, due to new technological advances and new techniques applied in medicine for diagnosis and treatment, serious and unexpected ethical conflicts took place in the United States related to the practice of medicine and clinical research (for example, the case in Seattle, and the Karen Ann Quinlan case [7-8]). It was then that the first bioethics centres were created: the Institute of Society, Ethics and the Life Sciences, Hastings Center (1969); the Joseph and Rose Kennedy Institute of Ethics for the Study of Human Reproduction and Bioethics (1971) in North America; and the Institut Borja de Bioètica (1975) in Europe. At this time the Belmont Report was published, proposing three fundamental ethical principles that aimed to protect patients and justify actions in clinical research: the principle of respect for people (autonomy), the principle of beneficence, and the principle of justice[9]. During the Eighties, following this publication, the bioethical discourse was mainly built on formulating ethical principles to act as a basis for medical practice and clinical research. Principles of Biomedical Ethics (1979)[10], Theory of Medical

6 Mark Siegler, "The Progression of Medicine. From Physician Paternalism to Patient Autonomy to Bureaucratic Parsimony," *Archives of Internal Medicine,* no. 145 (1985): 714.

7 Shana Alexander, "They Decide Who Lives, Who Dies," *Life,* no. 9 (1962): 103-25.

8 Supreme Court of New Jersey. *In re Quinlan. In the Matter of Karen Quinlan.* 1976.355 A.2d.647 (N.J.).

9 The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Washington DC: Department of Health, Education, and Welfare, 1979).

10 Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics* (New York: Oxford University Press, 1979).

Ethics (1981)[11], and The Foundations of Bioethics (1986)[12] include a common feature was the defense of principles and procedures to solve ethical conflicts in the clinical and welfare fields, in what we today understand as principlism.

The most established procedural bioethical approach is the one defended by Beauchamp and Childress. The objective of their theory is to offer a reference framework for moral discernment and decision making, and demonstrate how ethical theory can help solve ethical issues in healthcare. They argue that not all areas of morality can be introduced within the theory of virtue's framework and language without supposing to lose basic moral protection. Moral judgement based on virtue ethics tends to be less important than rights and procedures. This may happen in relationships between strangers, for example, when a patient meets their physician for the first time. Therefore, a reference moral framework was proposed, providing four ethical principles that facilitate a common moral language in the patient-physician relationship: The principles of autonomy, non-maleficence, beneficence, and justice.

Robert M. Veatch, influenced by John Rawls' contractual theory, justified a procedural bioethical theory on the basis of a triple contract[13]. In the face of ethical issues, the theory proposes a mixed strategy that includes a hierarchial or lexicographical order and weighting between several ethical principles. The lexicographical order is a serial order between principles that avoids having to level them, as there are those that have absolute value and remain without exception[14]. These principles are a result of different contracts between people who seek to find a moral foundation for human actions within the same society or moral community.

Another example of procedural bioethics is one proposed by H. Tristram Engelhardt. It is based on the assumption that a contemporary society is constituted by relationships between moral strangers — between people who do not share the same morality — and procedural bioethics allows coexistence between moral strangers as well as the creation of a moral community with a certain consensus among all. In other words, there are two moral discourses: the one between moral friends, and the one between moral strangers[15]. In order to achieve a moral

11 Robert M. Veatch, *A Theory of Medical Ethics* (New York: Basic Books, 1981).

12 Tristram H. Engelhardt, *The Foundations of Bioethics* (New York: Oxford University Press, 1986).

13 Robert M. Veatch, "Professional Medical Ethics: The Grounding of Its Principles," *Journal of Medicine and Philosophy* 4, no. 1 (1979): 14.

14 John Rawls, *Teoría de la Justicia* (Madrid: Fondo de Cultura Económica, 1995).

15 Tristram H. Engelhardt, *The Foundations of Bioethics* (New York: Oxford University Press, 1986).

discourse accepted by all parties it is necessary to reach an agreement between moral strangers. This agreement or moral consensus may be achieved with two principles of the first order: the principle of permission, also called the principle of moral authority, and the principle of beneficence.

Theories by Beauchamp, Childress, Veatch, and Engelhardt are clear examples of what we may call the procedural bioethical approach: those focused on procedures, rather than on content.

Content or Substantive Bioethics

The concept of "virtue" held a special relevance in the philosophy of ancient Greece, of the Middle Ages, and later on in the Scottish Sentimental School. However, interest then dropped so low that it has been described as a "neglected topic"[16], a concept forgotten by contemporary moral philosophy. It was not until 1958 when Elizabeth Anscombe wrote her article "Modern Moral Philosophy"[17] that new articles and books began to appear in which virtue returned to occupy the centre of attention of ethical theories. After Anscombe's article, several speeches were made that opposed the pre-eminence of concepts such as "moral duty", "norm" and, in general, those deontological theories that suffered from excessive formality. This criticism of defining the moral act as a fulfillment of a duty or moral rule, or with the calculation of consequences, gave rise to the re-birth of aretical ethical theories. In aretical ethical theories, the intention and will of humans precedes any action, and hence the pre-eminence of character and its content are the foundation of moral discernment, instead of a set of principles or rules.

Thus, a good act is not the result of acting according to a rule or principle, or after calculating that the benefits of an action outweigh its risks, or in accordance with a procedure. Instead it is the result of acting on a virtue to achieve good, requiring prior knowledge about what is good, rather than what is right. As Rosemarie Hursthouse summarises, an ethic of virtue is the one centered on the agent and takes into account aretic concepts such as "good" or "virtue", and not others, such as "right ", "duty" and "obligation". In addition, it rejects the idea that ethics can encode rules or principles that guide actions[18].

The same occured in the bioethics field: concepts like virtue and moral content were forgotten due to a preference for principles and procedures. Despite the danger

16 Lawrence Becker "The Neglect of Virtue," *Ethics* 85, no. 2 (1975): 110-122.

17 G. Elizabeth Anscombe, "Modern Moral Philosophy," *Philosophy* 33, no. 124 (1958): 1-19.

18 Rosalind Hursthouse, *On Virtue Ethics* (Oxford: Oxford University Press, 1999), 25.

of forgetting substantive bioethics or bioethics of content, there have been several authors who have focused their bioethics theories on the aretic approach[19-20].

One of the mainly content or substantive bioethical theories is the moral philosophy of medicine defended by Edmund D. Pellegrino and David Thomasma: a theory based on phenomenology of medicine, research on medical phenomena and its own content, such as the nature of health and disease, the logic of medical knowledge, or the nature of the patient-physician relationship. For Pellegrino, the ethics of medicine based on principles has certain shortcomings: "It leaves an inferential gap between principles and their application in concrete clinical cases. It is not convincing to physicians, because it is derived from philosophies external to medicine." [21] Therefore, a philosophy of medicine is needed to provide the basis for defining what good medicine is and where duties, obligations, and rules should be derived from.

Medicine is not just a theoretical science but also a practice and a moral activity, since actions must be good as well as correct. In the medical field we will always find uncertainty, and the good of the patient depends, ultimately, on the nature of each patient. In fact, both in diagnosis and in medical treatment this uncertainty is inevitable, since there is no direct connection between medical science and the patient, between theoretical knowledge and the nature of each case. The uncertainty is also felt by the physician as they may not always have full evidence about the best treatment, and not all of them are equally capable of making the best incision. That is why neither a principle nor a procedure will help the physician to perform the best incision, but a practical virtue to combat the medicical uncertainty, and knowledge about the the substantive content of the good of the patient, to combat the patient's uncertainty. As Pellegrino stated: "this irreducibility of the character of the moral agent, the physician in medical ethics, is a fact, regardless of the model of ethical reasoning one elects -principle- or rule-based, duty-based, casuistic, situational, emotivist, egoistic, intuitonist, and so on. In every ethical theory there comes a moment of opportunity, the use of the theory by a particular person in a particular circumstance. In that moment, the virtues will make the difference, making a good theory better in ameliorating the harm of erroneous theories."[22]

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19 James F. Drane, *Becoming a Good Doctor: The Place of Virtue in Medical Ethics* (Kansas City: Sheed & Ward, 1995).

20 Edmund D. Pellegrino and David C. Thomasma, *The Virtues in Medical Practice* (New York: Oxford University Press, 1993).

21 Edmund D. Pellegrino, "Medical Ethics: Entering the Post-hippocratic Era," *Journal of the American Board of Family Practice* 1, no. 4 (1988): 235.

22 Pellegrino and Thomasma, *The Virtues in Medical Practice,* 29.

This is an example of a content or substantive bioethical approach: focused on actual situational interactions and in the foundation rather than the formulation of procedures.

Conclusion: Towards a Complementary Approach

Despite the existence of various bioethical discourses, such as the ethics of virtue by Pellegrino and Thomasma, the case of Albert Jonsen[23], R. Tong's feminist approach [24], or the pragmatism defended by J.J. Fins and G. McGee[25], the persistent emergence of ethical conflicts in healthcare and clinical research has created the need for instruments that facilitate the decision making process. The resulting so-called bioethical principles and decision making procedures have become particularly important in the discipline of bioethics, thus confirming Pincoffs' hypothesis that the nature of time dictates what ethics there must be[26]. We could say that the greater interest in principles and procedural approaches rather than those of content is something logical and, in fact, natural in the current practice of medicine.

The pre-eminence of the procedural discourse confirms Pincoff's thesis when he affirmed that the most profitable for ethics, and also called for bioethics, are precisely the problems and situations that pose ethical issues: "There is a consensus concerning the subject matter of ethics so general that it would be tedious to document it. It is that the business of ethics is with problems, i.e. situations in which it is difficult to know one should do"[27], and this is, as Pellegrino stated, a risk: "Substantive ethics -defining and doing what is morally good- is in danger of being set aside in favour of procedural ethics -setting ethical conflicts in a morally defensible way."[28]

The essential trait of the procedural bioethical approach is that it focuses on the formulation of procedures that help solve ethical conflicts in clinical practice while respecting the principles and rules. As a result, correct action is carried out according to the procedure and any responsibility depends on compliance to the

23 Albert R. Jonsen, Mark Siegler, and William J. Winslade, *Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine* (New York: Macmillan Publishing Company, 1986).

24 Rosemarie Tong, *Feminist Approaches to Bioethics: Theoretical Reflections and Practical Applications* (Boulder: Westview Press, 1997).

25 Gleen McGee, ed., *Pragmatic Bioethics* (Nashville: Vanderbilt University Press, 1999).

26 Pincoffs, "Quandary Ethics," 555.

27 Pincoffs, "Quandary Ethics," 552.

28 Edmund D. Pellegrino, "Preface" in *Percival's Medical Ethics: Or, a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physician and Surgeons,* ed. C.D. Leake (Huntington: Robert E Krieger Publishing Co., 1975), 6.

procedure. Thus, the responsibility does not fall on the person but on rules and procedures. That is, there are not good or not so good decisions, but rather better or worse procedures. However, as Frankena stated, "principles without traits are impotent and traits without principles are blind"[29]. The same could be said for the procedural bioethical approach and the content or substantive bioethical approach, as both are complementary. In this way, Pellegrino and Thomasma agree that "virtue and principle-based theories in medical ethics must be closely linked with the nature of medicine itself, that is, with a philosophy of medicine."[30]. In other words, the philosophy of medicine is the discipline which may provide content to the procedural discourse[31].

In that sense, Beauchamp and Childress also agree to incorporate virtues and principles into the same discourse; for them "a moral philosophy is simply more complete if the virtues are integrated with principles. We have grounds to declare virtue theory and principlism partners rather than competitors."[32] Yet they still do not renounce giving greater prominence to principles and ethical norms since it cannot be pretended that all acts by a virtuous person are morally acceptable.

Bioethical principles have helped create a common discourse between healthcare professionals by facilitating a lingua franca[33] and an interdisciplinary dialogue, however procedures also need content because, by themselves, they do not exhaust the moral complexity of medicine. As Pincoffs said in defence, there are not rules but those who decide and act from their particular conception of good[34]. An example is Pellegrino's and Thomasma's content bioethical approaches, which offer a thoughtful discourse on the nature of medicine enabling the good of the patient to be defined, and to make both a correct and good decision for each particular patient.

In summary, a disjunction between content and procedural bioethical discourse is not recommended. Virtue discourse is what confers moral content to the procedural discourse, overcoming any emptiness of the principle, or as Leo R. Kass called it, its

29 William.K. Frankena, *Ethics (*Englewood Cliffs: Prentice-Hall; 1973), 65.

30 Pellegrino and Thomasma, *The Virtues in Medical Practice,* XII.

31 Pellegrino and Thomasma, *The Virtues in Medical Practice,* 53.

32 Tom L. Beauchamp, "Principlism and Its Alleged Competitors," *Kennedy Institute of Ethics Journal* 5, no. 3 (1995): 195.

33 Edmund D. Pellegrino, "The Four Principles and the Doctor-Patient Relationship: The Need for a Better Linkage" in *Principles of Health Care Ethics,* edited by a Raanan Gillon (New York: John Wiley & Sons, 1994), 360.

34 Pincoffs, "Quandary Ethics," 562.

procedural ingenuity[35]. The first is the set of bioethical theories giving prominence to virtue and placing greater interest towards the questions of foundation and content rather than the formulation of principles and procedures. The second is the one defended by those bioethical theories that, given the presence of ethical conflicts, facilitate decision-making processes to help find solutions and correct ways to act through the formulation of principles or procedures. Rather than rivals the approaches should be complementary, as the first overcomes any procedural ingenuity; while virtue ethics provide content, principlism and the procedural bioethics approach provides normativity.

35 Leon R. Kass, "Practicing Ethics: Where's the Action," *Hastings Center Report* 20, no. 1 (1990): 7.