Ethical evaluation as a driver for value-based choice of innovative technology

Paolo Petralia[1], Marco Doldi[2,3], Girolamo Mattioli[4,5]

[1]University of Genoa, Genoa, Italy; [2]General Direction of the Local Health Authority ASL4, Liguria; Italy; [3]Higher Institute of Religious Sciences, Genoa, Italy; [4]Pediatric Surgery Department, IRCCS, Istituto Giannina Gaslini, Genoa, Italy; [5]DINOGMI, University of Genoa, Genoa, Italy

Abstract. Demonstrating the effectiveness of using an innovative technique in medicine is a multifactorial objective: several integrated areas in which evidence and outcomes must be measured, both in the clinical-scientific and technical-organizational areas.

In relation to underlying costs and production tariffs, such representation is now standard practice in the HTA methodology, rather than in the management assessment and budget choices. What is occasionally assessed in this "value set-up" is the impact of the ethical choice and the contextual data dimension - environmental and interpersonal - and the subjective perception of all the actors in the process. The case of the introduction of robotics in paediatric surgery demonstrates - in an exemplary manner - how the ethical evaluation of the greater satisfaction for operator and patient, together with the benefit for the latter, even under the same conditions of safety and clinical outcome - can make the difference in the choice of operative technologies, even those of higher costs. Of course, the specific expertise of the operators is a prerequisite, as it is the demonstration that paediatric robotic surgery is safe, effective and improves performance and treatment outcomes: an original synthesis in the definition and enhancement of the specificity of the paediatric patient - who is not a 'small adult' - and of the paediatric hospital, which must guarantee the provision setting tailored to his or her needs.

Key words: minimally invasive surgery; paediatrics; paediatric robotic surgery; innovative technology

Objectives and methodology

The introduction of an innovative technology into clinical practice requires the prior demonstration of its safety and efficacy and its clinical-scientific and technical-organizational evidence and outcomes. It has also been necessary to enhance its efficiency: such representation, in relation to underlying costs and production tariffs, is now standard practice in the HTA methodology, rather than in the management assessment and budget choices.

What is occasionally assessed in this "value set-up" is the impact of the ethical choice and the contextual data dimension - environmental and interpersonal - and the subjective perception of all the actors in the process.

The case of the introduction of robotics in paediatric surgery demonstrates - in an exemplary manner - how the ethical evaluation of the greater satisfaction for operator and patient, together with the benefit for the latter, even under the same conditions of safety and clinical outcome - can make the difference in the choice of operative technologies, even those of higher costs.

After the preliminary demonstration that paediatric robotic surgery is safe, effective and improves performance and treatment outcomes, the opportunity to highlight the need for the specific competence of the operators, as well as the need for an operating en-

vironment (peculiar to the patient's characteristics) has been stressed.

The authors present an original synthesis in the definition and enhancement of the pediatric patient's specificity - who is not a 'small adult' - and of the paediatric hospital, which must guarantee the provision setting tailored to his or her needs (1).

Moreover, the need to allocate resources to a new medical technology cannot disregard a contextual multifactorial assessment of ethical content, which is - in some ways - decisive when used as a decision-making driver with substantially equal clinical outcomes.

Techno-ethical and bio-economic considerations

"If we wanted to summarize the reasons that can be adduced in favor of the fact that an ethics teaching is extremely appropriate for a medical student, we could indicate mainly three: [...] medicine is a human occupation that involves many types of actions, of which most have an ethical relevance, that is, they can be defined as morally just or unjust. Furthermore, medicine has as its purpose many fundamental human assets (life, health, the fight against pain, the defense of conscience and bodily integrity) which as such are morally relevant, are a source of moral duties." Finally, medicine is a profession, meaning by this a work activity that implies a high degree of specialization, and therefore involves very peculiar professional ethics, as evidenced by the existence of deontological codes and even professional oaths (2).

Ethical reflection in Medicine is therefore fundamental to the lifelong learning of health professionals, as a reference value framework for the choices they make in relation to the people with whom they establish a relationship, and - in particular - a care relationship (3).

A new horizon has opened up for this reflection, in the context of the introduction of new technological products. We only need to think about the use of robotics in surgery and in diagnostics and the therapeutic treatment of physical disabilities. In reality, all this constitutes an enhancement and improvement of medical practice. Now, research developments and their applications have been used in various human contexts and it has led to improvements and to questions about both man and human coexistence.

Biotechnology, nanotechnology, artificial intelligence and robotics represent the new frontiers that contemporary scientific knowledge has reached. They are referred to as 'emerging and converging' because of their increasing development and interaction with humans. They arouse admiration and interest because of the wide range of applications that they now allow in various fields, proving to be an effective human enhancement. They raise ethical questions about their use, as the Italian document 'Developments in robotics and roboethics' rightly points out. From an anthropological and theological point of view, they also raise interesting questions, such as: "What does it mean to be human - 'human' in an age of technological complexity and rapid change?" "How can technological development be managed?".

The extensive use of technology in the human world has long been referred to as 'transhumanism'.

The term was coined in 1957 by J. Huxley (1887-1975) and has gained increasing acceptance over time; it initially denotes the desire to empower humans through scientific knowledge and technological progress. N. Bostrom, founder of the "World Transhumanist Association", sees technology as a way of overcoming humanity's limited condition. Similarly, the "Transhumanist Declaration" (2009) considers how contemporary humanity produces artefacts interacting - externally and entirely - with man's being in its corporeal dimension. Technology is occupying the center of our existence: artificial intelligence and robotics have produced tools to increase human operational capacity (e.g. in surgery), devices to support vital functions (e.g. prostheses).

Without technologies, transhumanism would only resemble scientific fiction. First of all, gratitude must be expressed to scientists for their efforts and commitment to humanity. Besides, all this progress raises a philosophical question, as H. Jonas (1903-1993) had already foreseen, stating that the new possibilities offered by biology give the well-founded idea of reshaping man's constitution and designing our descent (4). If such a revolution were to take place if technological power were to really begin to tinker with those elementary keys on which life will have to play its melody for generations - perhaps the only melody of its kind in the

universe - then a reflection on what is humanly desirable and what should determine its choice - in short, a reflection on the image of man" - will become more imperious and pressing than any other reflection ever demanded of mortal reason" (Technology, Medicine and Ethics). It is necessary to bear in mind what the human person is, their purpose and their improvement. In the face of these questions, it must be ascertained whether technology is really able to answer them. "Science and technology have helped us to deepen the boundaries of our knowledge of nature, and in particular of the human being. But they alone cannot provide all the answers. Yes, science is a road to the true [...] it is a fraternal service, but on its own it cannot give a complete answer to the problem of meanings'. It is necessary for anthropology and ethics to explain the purpose of technology: technoethics is born.

In their daily work, doctors are increasingly called upon to make decisions based on 'economic' choices.

Ethical choice promotes man in his fullness: but if the concept of humanitas is inseparable from that of ethics, what space is it possible to recover the existence of value systems in subjects who make economic choices?

Reflecting on the relevance of ethical principles before economic reflection, we can highlight three cases: "If we think that the existence of a system of value foundations is relevant for assessing the overall functioning of the economic mechanism of resource allocation, then the relationship between the sphere of values and the economic sphere can be of at least three kinds: external relevance of meta-economic ethical principles to the model of market functioning; internal relevance of such principles; internal relevance of an ethics of the economy.

In the first case - external relevance of meta-economic ethics - the value system can be considered as external to the economic model, and with respect to it, it stands as a logical prius, necessary to evaluate the premises and results of the model itself, with purposes other than efficiency in the strict sense. The ethical foundations, without the need to contradict the operating principles of the mechanism of optimal allocation of resources, make it possible to evaluate the premises and results, suggesting possible non-economic interventions.

In the second case - internal relevance of a meta-economic ethic - the value system permeates and conditions the very principles that regulate and direct the choices of resource allocation, so that the application of the principle of efficiency is conditioned, or, in the most extreme cases, denied.(...)

There is then a third way, which can also be complementary to the first configuration of the relations between values and economy: "it is necessary to consider the possibility of the existence of a minimum set of value rules within the very functioning of the model of economic analysis, based precisely on the principle of efficiency. In other words, it is necessary to take note of the existence of a market ethic" (5).

The search for reunification of ethics with economics through a broader moral code of evaluation that goes beyond the efficiency of results starts from a renewed interest in the revaluation of ethical values also dictated by an unusual fundamental "responsibility" (4) towards the environment and future generations, based on the new doctrinal approaches, passing from the egalitarian system of Rawls, theorist par excellence of justice and inviolability of the individual, to the substantial approach of A. Sen, convinced supporter of the re-appropriation of ethics by the economy.

It is therefore understood that the ethical evaluation can be summarized as the valorization of man as an actor and beneficiary of action, in this case, a therapeutic one, which adopts innovative technologies on the basis of and within a value and personalized reference context: "There can indeed be a sustainable market ethic without betraying adherence to value principles"(5).

Paediatric specificity in robotic surgery

The application of robotics in paediatric surgery is recent, and particularly lacking in Health Technology Assessment impact analyses that have defined its standardization and management adoptability.

The practice of adopting this technology mainly in a standard way and standard contexts (hospitals and general surgery centers) brings with it evidence of the lack of a dimension of paediatric specificity, both in terms of the importance of a specialized structure with

dedicated staff and equipment and protocols in the care of the paediatric patient, meeting his or her needs and including the family in the care pathway. The child is not a 'small adult', and requires tailor-made environments, people and equipment (6).

The experience developed at the University Centre for Paediatric Robotic Surgery at the IRCCS Giannina Gaslini in Genoa has deepened such evolution in recent years in technical, cultural and educational terms, outlining some essential dimensions of sustainability (7).

First of all, the verification of the use of the robotic system in the patient and the paediatric hospital in complete safety: the strategies adopted for the positioning of the trocars and robotic arms have proved to be effective and none of the conversions or postoperative complications observed so far in the reference Paediatric Robotic Surgery Centre have occurred because of technical difficulties due to the adaptation to the paediatric patient or problems related to robot dysfunctions (8,9).

Secondly, the use of the robot in the different cohorts of patients: patients of very different ages were treated, from 4 months to 22 years, with very different pathological conditions, from congenital malformations to benign or malignant neoplastic resections, and involving at least four surgical fields (urological, gastroenterological, oncological, thoracic).

Lastly, special consideration must be given to the complexity of the patients treated, mainly linked to the comorbidity present at the time of surgery, for half of the ASA ≥2 and ASA ≥3 patients: according to the inclusion criteria in adult hospitals, more than half of the patients would have been excluded, with an obvious ethical impact that is not negligible (10).

It, therefore, seems essential that the care of paediatric patients with innovative technologies be entrusted to staff experienced in treating this type of patient and in a hospital that places the specificity of paediatric care at the centre of its activities.

Economic sustainability

The cost of each surgical procedure includes, in a simplified manner, the management of hospitalization, the cost of the personnel employed and the cost of using specific disposable and non-disposable devices and materials (11).

For each robotic procedure, an additional cost - compared to the procedure performed in conventional minimally invasive surgery - was estimated to be between €2,760.00 and €5,360.00, with an average of €4,250.00.

The cost of each type of procedure compared with the corresponding DRG (diagnosis related group) to which it belongs (each group of procedures belonging to a specific DRG corresponds to an economic value "reimbursed" by the National Health System to the hospital structure at the end of the hospitalization) shows how the cost of each procedure performed with a non-robotic technique is already higher than what is expected and "reimbursed" according to DRGs, and how this inevitably increases with the use of the robotic system (12).

The result would be an acknowledgement of the diseconomies of choosing robotic over traditional minimally invasive surgery.

On the other hand, he analysis of outcomes should lead to a reassessment of economic sustainability, although there is no economic analysis in the literature to support this.

A robotic system, in fact, makes procedures easier even for surgeons less experienced in minimally invasive surgery, increases the number of procedures that can be performed minimally invasively that would otherwise only be performed in open, increases the number of cases treated and thus leads to higher volumes and more expertise developed, improves outcomes and develops greater attractiveness for the hospital: all these consequences of using a robotic system could lead to revenues that equal the economic cost (7).

The choice of whether or not to adopt an innovative technology such as robotics in paediatric surgery based solely on cost-effectiveness and efficiency analysis remains open.

Concluding remarks

After examining the technological characteristics, efficacy in clinical practice and safety, and finally dealing with economic sustainability, it is possible to say

that the objective determinants of the choice of whether or not to adopt the new technology of paediatric robotic surgery may be the potential and actual effects of the new technology before and during its use, and the consequences of patient's inclusion or exclusion for the healthcare system, the economy and society.

Furthermore, demonstrating the feasibility and validity of using the robotic system in the paediatric age is strongly related to the importance of the specificity of paediatric operators and in the paediatric hospital (13).

In fact, we do not intend to argue only the usefulness of the robotic system, since there are reports of studies conducted mainly on adult patients who have already claimed the benefits of robotic surgery. On the contrary, we want to underline that, despite the widening of the literature and the greater diffusion of the robotic technology in an increasing number of surgical disciplines, the paediatric surgical experiences are much less known globally. However, the use on children is increasing also at international level. This is, of course, since urological and general surgical procedures on adults have been increasing dramatically for about two decades, but the widespread use on the paediatric population is a relatively recent phenomenon (1).

As far as characteristics and efficacy are concerned, the robotic system undoubtedly has considerable advantages: the procedures under study, if carried out traditionally, are demanding for the surgeon both from the point of view of the executive technique and the necessary skills and for the physical effort required, so much that some procedures are usually carried out in open and not in laparoscopy or thoracoscopy (e.g. tracheopexy); the robotic system guarantees greater simplicity of execution for the surgeon, especially as regards visibility and accessibility in the spaces that are more difficult to reach in laparoscopy, and very often a better outcome (14).

Patient *safety* considerations are relevant, related to the already described variability in patient size and weight, from infants to adolescents. For the latter, strategies superimposable on those chosen for adults can be easily implemented, but younger children require tailor-made strategies, very often created *ad hoc* given the high complexity of the patient, such as the positioning of trocars at distances appropriate to the size of the child: obviously, it requires a scientifically recognized standardization. It would also be essential to overcome the other technical limitations of the robotic system applied to the paediatric patient, by adapting the size of the instruments that are still only available in 8mm. Therefore the adaptation of the system to the paediatric patient is not only possible, but increasingly desirable (15).

Economic viability is ultimately the limiting factor in the choice: to invest in new technologies it is necessary to assess the availability of resources, which are often limited. And in a situation where a new technology has a high cost-benefit ratio, if the availability of resources is limited, the offer cannot be made equally to everyone who needs it.

The impact ethical choice's impact seems to be decisive, both with regard to the dimension of contextual data - environmental and interpersonal - and the subjective perception of all the actors in the process.

The case of the introduction of robotics in paediatric surgery demonstrates - in an exemplary manner - how the ethical evaluation of the greater satisfaction for operator and patient, together with the benefit for the latter, even under the same conditions of safety and clinical outcome - can make the difference in the choice of operative technologies, even those of higher costs (7).

We, therefore, believe that the decision to allocate resources to new medical technology cannot disregard a contextual multifactorial assessment of ethical content - a reflection that deserves a specific study - which is - in some ways - decisive when used as a decision-making driver with substantially equal clinical outcome and variable cost-effectiveness conditions.

References

1. Richards HW, Kulaylat AN, Cooper JN, McLeod DJ, Diefenbach KA, Michalsky MP. Trends in robotic surgery utilization across tertiary children's hospitals in the United States. Surg Endosc. 2020; DOI: 10.1007/s00464-020-08098-y
2. Premoli De Marchi P. Introduzione all'etica medica. Torino: Accademia University Press; 2013.
3. Ciliberti R., Alfano L, Baldelli I, De Stefano F, Bonsignore A. Self-determination, healthcare treatment and minors in Italian clinical practice: ethical, psychological, juridical and

medical-legal profiles, Acta Biomedica 2018; 89(1):34–40
4. Jonas H. The Imperative of Responsibility: In Search of an Ethics for the Technological Age. Chicago, The University of Chicago Press; 1985
5. Fiore MA. L'agire economico tra efficienza ed equità: un breve excursus teorico. Quaderno 2017; 17. https://www.economia.unifg.it/sites/sd01/files/allegatiparagrafo/29-11-2016/q172007.pdf
6. Bruns N E, Soldes O S, Ponsky T A. Robotic Surgery-may Not "Make the Cut" in pediatrics. Front Pediatr 2015; 3(10):1–3
7. Mattioli G, Petralia P. Pediatric Robotic Surgery: Technical and Management Aspects. 2017.- Berlino: Springer Nature.
8. Mattioli G, Petralia P. From laparoscopy to robotic surgery: Sense and nonsense. In Pediatric Robotic Surgery: Technical and Management Aspects, 2017: 3–8
9. Dindo D, Demartines N, Clavien P A. Classification of Surgical Complications: A New Proposal With Evaluation in a Cohort of 6336 Patients and Results of a Survey. Ann Surg 2004; 240(2):205–13.
10. Mattioli G, Pini Prato A, Razore B, Leonelli L, Petralia P, Pio L, et al. Da Vinci robotic surgery in a pediatric hospital. J Laparoendosc Adv Surg Tech 2017; 27(5):539–45
11. Petralia P, Buffi NM, Cardone P, Rosati U, Barabino P, Pio L, Mattioli, G. Pediatric Robotic Surgery: Technical and Management Aspects. In: Mattioli G, Petralia P (Eds) Management aspects, cost analysis and training; 2017: 9–14.
12. D'Souza M, Gendreau J, Feng A, Kim LH, Ho A L, Veeravagu A. Robotic-Assisted Spine Surgery: History, Efficacy, Cost, And Future Trends. Robotic surgery: Research and Reviews 2019; 6: 9-23.
13. Mattioli G, Petralia P. Preface. Pediatric Robotic Surgery: Technical and Management Aspects, 2017:VII
14. Lane T. A short history of robotic surgery. Ann R Coll Surg Engl 2018; 100(6):5–7.
15. Mattioli G, Pio L, Leonelli , Petralia P, Pini Prato, A. A provisional experience with robot-assisted Soave procedure for older children with hirschsprung disease: Back to the future? J Laparoendosc Adv Surg Tech 2017, 27(5):546–549.

Correspondence:
Paolo Petralia
Institute Giannina Gaslini
Children's Hospital, Italy
E-mail: paolo.petralia@edu.unige.it