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COMMENTARY
Assent, consent and paediatric bioethics

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Abstract
In the ethics of relations between physicians and paediatric patients the question of autonomy and its corollary, consent, is crucial. While the importance attached to autonomy in the clinical setting is not the same as that accorded in research, it nonetheless assumes greater relevance when minors are involved, and a careful case-by-case assessment becomes obligatory.

Key words
- autonomy
- child
- informed consent
- medical deontology
- paediatrics

In a book published in 1977 that describes the passage from research to clinical practice of various basic scientific discoveries the author, Julius Comroe, suggested using a fictional "retrospectoscope" in order to study these transformations from the past to the present [1].

Our understanding of the present situation of medicine and bioethics can often be improved by looking at the past. This Commentary is an attempt to use a "retrospectroscope" to analyse certain ethical attitudes towards relations with paediatric patients; it is inspired by, among others, a dossier devoted entirely to this issue by the journal "Medic" [2].

The emergence of paediatrics as a separate discipline can be traced to the end of the 18th century, and in 1802 Professor Gaetano Palloni became the world's first holder of a Chair of Paediatrics, at the University of Pisa: Italy had already made a mark in the sector with the Western world's first book on paediatrics, written by a physician, Paolo Baggelardo, and published in Padua in 1472.

Although bioethics is well rooted in the history of human culture, it took much longer to establish itself as a distinct field of study, the term "Bioethics" being proposed by Van Rensselaer Potter in a well known article published in 1970 in "Perspectives in Biology and Medicine" [3] and further elucidated in an equally well known book [4] published the following year.

The ethics of relations between physicians and patients clearly predates the birth of the science of bioethics, and several old texts [5] refer to the issue even before the time of Hippocrates. The Corpus Hippocraticum and the Hippocratic Oath were the first chapter in the history of medical ethics through the centuries and up to the present day [6]. The arrival of bioethics provided a fundamental boost to medical ethics and to the deontology of physician-patient relations in particular. One of the key factors in this was the set of principles proposed in the "Belmont Report" [7] and the "Principles of Biomedical Ethics" [8] by Tom Beauchamp and James Childress, both of which are now universally recognised as reference texts on bioethical issues: respect for persons (referred to as "respect for autonomy" in the "Principles of Biomedical Ethics"); beneficence and non-maleficence (linked together in the "Belmont Report") and justice.

The ethics of relations between physicians and patients (including paediatric patients [9]) attributes special importance to the principle of autonomy and, in consequence, to consent [10]. The main requirements of consent are: disclosure, capacity and voluntariness [11].

Regulations generally envisage that until a child reaches his or her majority, consent should be obtained from the parents or the child's legal guardian [12]. While the responsibility for decision-making rests with the parents or whoever is acting *in loco parentis*, it is generally stipulated that whenever a minor is sufficiently able to understand the information he or she is given and to express an informed decision, his or her assent should not only be sought but should also be given proper consideration [13]. The notion of "paediatric assent" was proposed by Sanford Leikin [14, 15] in the 1980s and was adopted in 1995 by the American Academy of Pediatrics [16].

The literature on these issues is abundant and much of it is concerned with legal aspects, or with theoretical disquisitions on the notion of autonomy. However, empirical data are now available on children's competence to give consent. Hein *et al*, for instance, conducted a survey involving 161 paediatric patients and demonstrated that the children's decision-making capacities regarding clinical research could be validly assessed us-

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ing the modified MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) [17]. MacCAT-CR is a semi-structured questionnaire prepared by Appelbaum and Grisso in 2001 [18]. Their study aimed to estimate the age limits for children to be deemed competent to decide on participation in research: children of 11.2 years and above generally appeared to be competent, while those of 9.6 years and younger were not. Children between 9.6 and 11.2 years were in a phase of transition in which they possess significant capacities but are not yet sufficiently mature.

While there is broad agreement that the consent procedure in a paediatric setting should include both the parental permission and the assent of the child (when he or she is competent to understand and to express an informed decision), the positions regarding the importance and role attached to that decision differ [19]. In some countries the decision of a minor carries the same weight as that of the parents or their representatives. In the Netherlands, for instance, a dual consent procedure is followed for children from the age of 12 [20]: two separate and equally valid informed consent forms are acquired, one from the parents and one from the minor, and both must be signed. In the event of a disagreement every effort must be made to reach agreement. Children depend on parents and caretakers for the decision. Nevertheless, the shift of parent orientation to peer orientation in adolescence should be assessed.

All of the above suggests a number of considerations, three of which are the following:

1. while adults are generally presumed to be competent, unless the physician is able to demonstrate the contrary, when minors are involved the opposite is generally the case. Although studies such as that by Hein, mentioned above, offer empirical data regarding the age at which it is reasonably possible to assume that a minor has the capacity to give consent, the subjective variables are so many and of such a nature that a case-by-case assessment is needed: an arbitrary chronological age might be replaced by a check of maturity of the child to understand the nature of the decision to be made and the consequences likely to follow from the selection of the available options. Parents and physicians play a key role in assessing the capacity;
2. tools such as the MacCAT-CR and other similar scales can be useful when quantifying a person's capacity to consent, but they are based mainly on the capacity to reason in a rational way and exclude other considerations (such as emotional aspects) that undoubtedly have a profound effect on a minor's capacity to consent [21];
3. the current emphasis on the principle of autonomy – and, therefore, of consent – should not be allowed to obscure the fact that while the respect for autonomy certainly has a key role in research, its role in clinical practice is not equally important, or at least not in the same sense. This is even more true when paediatric patients are involved. In the research setting, moreover, a distinction has to be made between non-interventional and interventional research. In the former case, as, for example, when biological samples stored in biobanks are being used in research projects, minor subjects may be granted greater autonomy: some authors consider that disputes about the withdrawal of information that is about both a parent and a child "should be resolved in favour of the child" [22]. In the latter case it is instead appropriate to attribute greater weight to the wishes of the parents or of their representatives, in the best interest of the minor.

Conflict of interest statement

No conflict of interest.

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